

#### HUD Lead Hazard Control Clearance Survey January 24, 2018

HUD's Office of Lead Hazard Control and Healthy Homes (OLHCHH) administers several grant programs, including lead hazard control (LHC) grants intended to eliminate lead-based paint hazards from low-income housing. LHC projects can span a range of activities, including abatement of lead-based paint, abatement of lead-based paint hazards, interim controls, and paint stabilization. Grantees are typically state or local government agencies who hire contractors to perform the work. At the completion of the LHC, housing units must be tested for dust-lead, and achieve clearance levels.

In response to the 2009 petition to EPA to revise the dust-lead hazard standards, HUD submitted an ICR to OMB to conduct a survey to determine the actual dust-lead levels routinely achieved following lead hazard control projects using current tools, methodologies, and systems (e.g., wet detergent wash, HEPA vacuuming, sealing or replacing flooring, sealing windowsills, installing window trough liners). The survey was conducted in 2015. HUD requested that all recipients of LHC grants from FY 2010, 2011, and 2012 complete a questionnaire and provide data on the actual clearance levels achieved for a random sample of housing units where work was conducted. Seventy-nine percent of the grantees completed the survey, providing data from 7,211 floor samples, 4,893 windowsill samples, and 2,787 window trough samples from 1,552 housing units.

Tables 1 through 3 show that most units passed clearance on the first try following cleaning and other actions in preparation for clearance testing. A small percentage failed on the first try, and an even smaller percentage failed on the second try. In the case of a failure, it is up to the contractor to determine what work practices to use to achieve clearance. In the fraction of jobs that failed to achieve initial clearance, the vast majority were able to achieve clearance using only additional cleaning and/or sealing, which are relatively simple practices.

Table 4 and Figures 1 through 3 show that HUD LHC grantees in the survey routinely achieved much lower clearance levels than the current standards. In particular, a final floor clearance level of  $10~\mu g/ft2$  was achieved in over 85% of cases even though the grantees were only attempting to clear at  $40~\mu g/ft2$ . Window sills achieved a clearance level of  $100~\mu g/ft2$  in 97% of cases, and troughs achieved this level in 94% of cases.

HUD concluded that a reduction in clearance level as requested in the original petition to EPA is technically feasible using the methods currently employed by HUD LHC grantees to prepare for clearance.

On the basis of this study, in 2017, HUD OLHCHH issued policy guidance requiring its Lead-Based Paint Hazard Control (LBPHC) and Lead Hazard Reduction (LHRD) Demonstration grantees to use Dust Hazard Action Levels of  $10~\mu g/ft^2$  for floors and  $100~\mu g/ft^2$  for windowsills. They are also required to use Clearance Action Levels of  $10~\mu g/ft^2$  for interior floors,  $40~\mu g/ft^2$  for porch floors,  $100~\mu g/ft^2$  for windowsills, and  $100~\mu g/ft^2$  for window troughs. These action levels only apply to these grant programs, not all housing units subject to HUD's Lead Safe Housing Rule (LSHR).

Action	Fraction of Total		
Actions Taken for Units Failing the 1st Try Only (12.2% of units)			
a. Re-cleaning	82.7%		
b. Sealing	13.8%		
c. Replacement	0.9%		
d. Overlaying	0.4%		
e. Other	2.2%		
Totals	100%		
Actions Taken for Units Failing Both the 1st and 2nd T	ry (1.7% of units)		
a. Re-cleaning	66.7%		
b. Sealing	18.2%		
c. Replacement	6.1%		
d. Overlaying	3.0%		
e. Other	6.1%		
Totals	100%		

Table 2. Actions Taken After Clearance Failures on Windowsills				
Activity	Fraction of Total			
Actions Taken for Units Failing the 1st Try Only (3.1% of units)				
a. Re-cleaning	75.9%			
b. Sealing	14.8%			
c. Replacement	0.0%			
d. Other	9.3%			
Totals	100%			
Actions Taken for Units Failing Both the 1st and 2nd Try (0.3% of units)				
a. Re-cleaning	75.0%			
b. Sealing	0.0%			
c. Replacement	0.0%			
d. Other	25.0%			
Totals	100%			

Table 3. Actions Taken After Clearance Failures on Window Troughs				
Action	Fraction of Total			
Actions Taken for Units Failing the 1st Try Only (1.7% of units)				
a. Re-cleaning	93.1%			
b. Sealing	6.9%			
c. Replacement	0.0%			
d. Install trough liner	0.0%			
e. Other	0.0%			
Totals	100%			
Actions Taken for Units Failing Both the 1st and 2nd Try	(0.1% of units)			
a. Re-cleaning	100.0%			
b. Sealing	0.0%			
c. Replacement	0.0%			
d. Install trough liner	0.0%			
e. Other	0.0%			
Totals	100%			

Floors		Window Sills		Window Troughs	
Level	Percent	Level	Percent	Level	Percent
< 40*	100%	< 250*	100%	< 400*	100%
< 20	94%	< 100 **	<u>&gt;</u> 97%	< 150	<u>&gt; 97%</u>
< 15	90%	< 80	> 96%	< 100 **	> 94%
< 10 **	85%	< 60	> 91%	< 80	> 92%
< 5	72%	< 40	> 87%	< 40	> 82%

Figure 1. Cumulative Distribution of Final Floor Clearance Levels (µg/ft²)

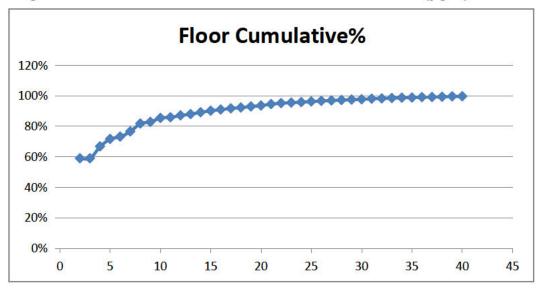


Figure 2. Cumulative Distribution of Final Window Sill Clearance Levels (µg/ft²)

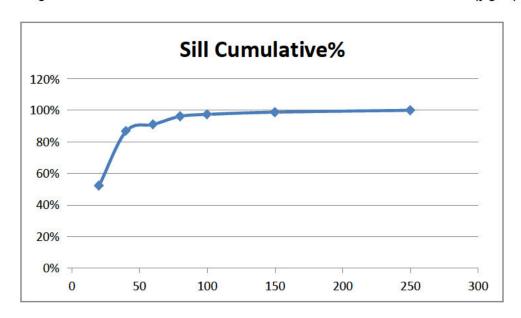
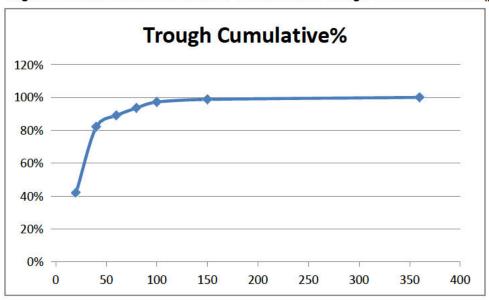


Figure 3. Cumulative Distribution of Final Window Trough Clearance Levels (µg/ft²)



#### **DLHS Regulatory Impacts Discussion**

February 8, 2018

**Lead-based paint hazard** means hazardous lead-based paint, dust-lead hazard or soil-lead hazard as identified in §745.65.

#### Subpart D- Lead-based Paint Hazards

§745.61 Scope and applicability.

- (a) This subpart identifies lead-based paint hazards.
- (b) The standards for lead-based paint hazards apply to target housing and child-occupied facilities.
- (c) Nothing in this subpart requires the owner of property(ies) subject to these standards to evaluate the property(ies) for the presence of lead-based paint hazards or take any action to control these conditions if one or more of them is identified

#### Subpart E- Residential Property Renovation (RRP)

§745.80 Purpose.

This subpart contains regulations developed under sections 402 and 406 of the Toxic Substances Control Act (15 U.S.C. 2682 and 2686) and applies to all renovations performed for compensation in target housing and child-occupied facilities. The purpose of this subpart is to ensure the following:

- (a) Owners and occupants of target housing and child-occupied facilities **receive information on lead-based paint hazards** before these renovations begin; and
- (b) Individuals performing renovations regulated in accordance with §745.82 are properly trained; renovators and firms performing these renovations are certified; and the work practices in §745.85 are followed during these renovations.

Anticipated impact: (b)(5) Deliberative Process

# Subpart F—Disclosure of Known Lead-Based Paint and/or Lead-Based Paint Hazards Upon Sale or Lease of Residential Property

§745.100 Purpose.

This subpart implements the provisions of 42 U.S.C. 4852d, which impose certain requirements on the sale or lease of target housing. Under this subpart, a seller or lessor of target housing shall disclose to the purchaser or lessee the presence of any known lead-based paint and/or lead-based paint hazards; provide available records and reports; provide the purchaser or lessee with a lead hazard information pamphlet; give purchasers a 10-day opportunity to conduct a risk assessment or inspection; and attach specific disclosure and warning language to the sales or leasing contract before the purchaser or lessee is obligated under a contract to purchase or lease target housing.

§745.101 Scope and applicability.

This subpart applies to all transactions to sell or lease target housing, including subleases, with the exception of the following:

- (a) Sales of target housing at foreclosure.
- (b) Leases of target housing that have been found to be lead-based paint free by an inspector certified under the Federal certification program or under a federally accredited State or tribal certification program. Until a Federal certification program or federally accredited State

certification program is in place within the State, inspectors shall be considered qualified to conduct an inspection for this purpose if they have received certification under any existing State or tribal inspector certification program. The lessor has the option of using the results of additional test(s) by a certified inspector to confirm or refute a prior finding.

(c) Short-term leases of 100 days or less, where no lease renewal or extension can occur.

(d) Renewals of existing leases in target housing in which the lessor has previously disclosed all information required under §745.107 and where no new information described in §745.107 has come into the possession of the lessor. For the purposes of this paragraph, renewal shall include both renegotiation of existing lease terms and/or ratification of a new lease.

Anticipated impact: (b)(5) Deliberative Process	

# **Subpart L—Lead-Based Paint Activities (evaluation and abatement)** §745.220 Scope and applicability.

- (a) This subpart contains procedures and requirements for the accreditation of training programs for lead-based paint activities and renovations, procedures and requirements for the certification of individuals and firms engaged in lead-based paint activities, and work practice standards for performing such activities. This subpart also requires that, except as discussed below, all lead-based paint activities, as defined in this subpart, be performed by certified individuals and firms.
- (b) This subpart applies to all individuals and firms who are engaged in lead-based paint activities as defined in §745.223, except persons who perform these activities within residential dwellings that they own, unless the residential dwelling is occupied by a person or persons other than the owner or the owner's immediate family while these activities are being performed, or a child residing in the building has been identified as having an elevated blood lead level. This subpart applies only in those States or Indian Country that do not have an authorized State or Tribal program pursuant to §745.324 of subpart Q.
- (c) Each department, agency, and instrumentality of the executive, legislative, and judicial branches of the Federal Government having jurisdiction over any property or facility, or engaged in any activity resulting, or which may result, in a lead-based paint hazard, and each officer, agent, or employee thereof shall be subject to, and comply with, all Federal, State, interstate, and local requirements, both substantive and procedural, including the requirements of this subpart regarding lead-based paint, lead-based paint activities, and lead-based paint hazards.
- (d) While this subpart establishes specific requirements for performing lead-based paint activities should they be undertaken, <u>nothing in this subpart requires that the owner or occupant un</u>dertake any particular lead-based paint activity

occupant undertake any particular lead-based paint activity	
Anticipated impacts: (b)(5) Deliberative Process	
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#### Subpart Q—State and Indian Tribal Programs

§745.320 Scope and purpose.

- (a) This subpart establishes the requirements that State or Tribal programs must meet for authorization by the Administrator to administer and enforce the standards, regulations, or other requirements established under TSCA section 402 and/or section 406 and establishes the procedures EPA will follow in approving, revising, and withdrawing approval of State or Tribal programs.
- (b) For State or Tribal lead-based paint training and certification programs, a State or Indian Tribe may seek authorization to administer and enforce §§745.225, 745.226, and 745.227. The provisions of §§745.220, 745.223, 745.233, 745.235, 745.237, and 745.239 shall be applicable for the purposes of such program authorization.
- (c) A State or Indian Tribe may seek authorization to administer and enforce all of the provisions of subpart E of this part, just the pre-renovation education provisions of subpart E of this part, or just the training, certification, accreditation, and work practice provisions of subpart E of this part. The provisions of §§745.324 and 745.326 apply for the purposes of such program authorizations.
- (d) A State or Indian Tribe applying for program authorization may seek either interim approval or final approval of the compliance and enforcement portion of the State or Tribal lead-based paint program pursuant to the procedures at §745.327(a).
- (e) State or Tribal submissions for program authorization shall comply with the procedures set out in this subpart.
- (f) Any State or Tribal program approved by the Administrator under this subpart shall at all times comply with the requirements of this subpart.
- (g) In many cases States will lack authority to regulate activities in Indian Country. This lack of authority does not impair a State's ability to obtain full program authorization in accordance with this subpart. EPA will administer the program in Indian Country if neither the State nor Indian Tribe has been granted program authorization by EPA.

Anticipated impacts: (b) (5)

#### Lead Rule Impacts and Cost/Benefits February 8, 2018

#### CURRENT RULEMAKING (RESPONSE TO NINTH CIRCUIT COURT DECISION)

#### (1) HAZARD STANDARDS

#### (A) HUD Lead-Safe Housing Rule

- (i) Affected Housing Universe: Housing subject to certain requirements of the HUD Lead-Safe Housing Rule (LSHR), specifically:
- Subpart C (Disposition of a residential property by a federal agency other than HUD)
- Subpart D (Project-based assistance >\$5000 provided by federal agency other than HUD)
- Subpart G (Multi-family mortgage insurance except conversions and major rehabilitations)
- Subpart H (Project-based assistance for multi-family properties receiving more than \$5,000)
- Subpart I (HUD-owned multi-family properties)
- Subpart J (Properties receiving \$5,000 to \$25,000 in rehabilitation assistance)
- Subpart J (Properties receiving more than \$25,000 in rehabilitation assistance)

Depending on the subpart that applies, properties may receive a visual assessment, a lead-based paint inspection, and/or a risk assessment (which includes dust sampling).

(ii) Affected Events: Pre-1978 housing units subject to LSHR that will test their dust-lead levels as part of a risk assessment and have results that fall between the existing hazard standards and the potential new levels ((5) (5)



#### (B) Elevated Blood Lead Level Investigations

- (i) Affected Housing Universe: Housing units with children who have been tested and found to have elevated blood lead levels. Many states and certain federal programs (Medicaid and CHIP) require blood lead screening for children. An environmental investigation is triggered for children with blood lead levels above a threshold value (varying from 5 μg/dL to 25 μg/dL, depending on the state).
- (ii) Affected Events: Pre-1978 housing units that will test their dust-lead levels as part of a risk assessment and have results that fall between the existing hazard standards and the potential new levels (b) (5)

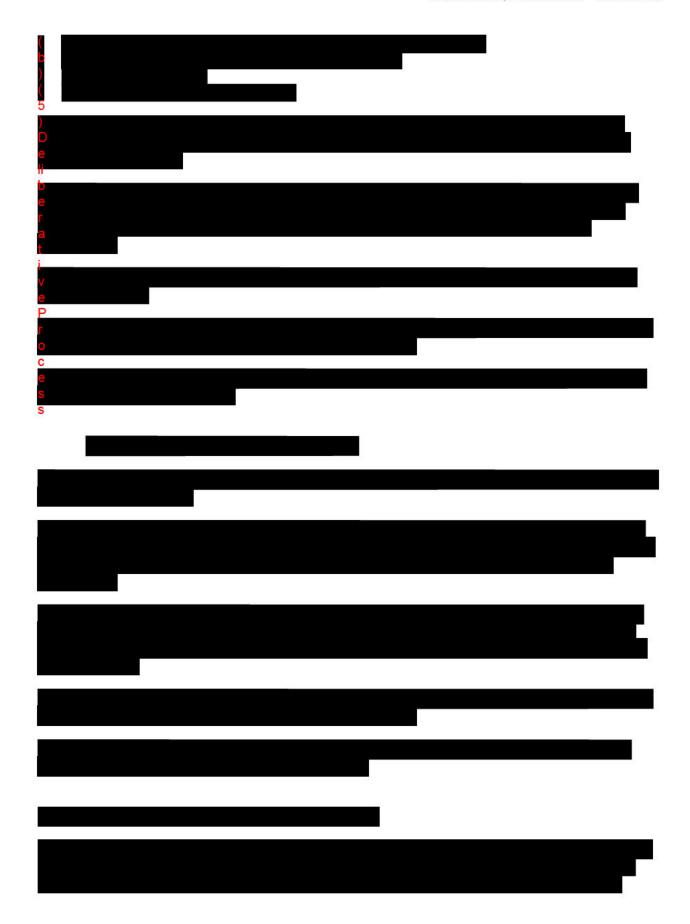


#### (C) EPA Real Estate Disclosure Rule

Sellers and lessors must disclose to the purchaser or lessee the existence of any available records or reports pertaining to lead-based paint and/or lead-based paint hazards. (Sellers and lessors are not required to generate any new testing data.) This means that records of dust testing must be disclosed regardless of what the results are. (b)(5) Deliberative Process

# POTENTIAL IMPLICATIONS FOR OTHER LEAD RULES – NOT PART OF CURRENT RULEMAKING

(b)(5) Deliberative Process





## $Chemours/GenX\ Briefing\ Paper-Non-CBI$

Office Director Pre-Briefing: 2:00PM, February 2, 2018 DAA Briefing: 12:00PM, February 7, 2018



(b) (7)(A)



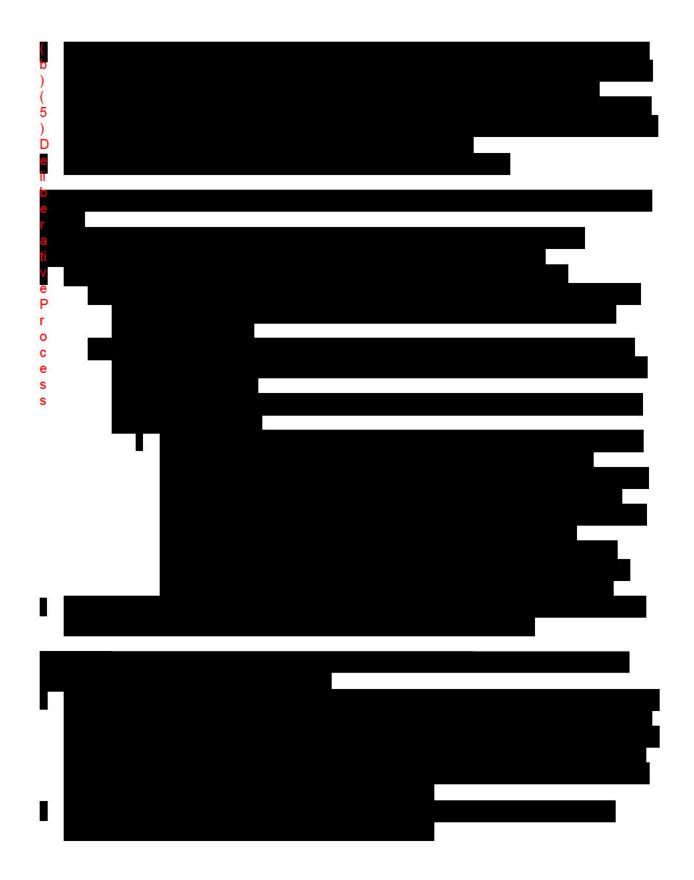
## LCPFAC Significant New Use Rule; Supplemental Proposal

#### Background

- The supplemental proposal on long-chain perfluoroalkyl carboxylate (LCPFAC) chemical substances is being issued to conform the lifting of the articles exemption to be consistent with amended TSCA and the added subsection 5(a)(5), Article Consideration.
  - EPA had proposed to lift the articles exemption in the January 21, 2015 SNUR; however, it was not for specific categories as amended TSCA now requires.

#### DAA Questions on Supplemental LCPFAC SNUR Proposal







#### Appendix 1

Excerpt from the proposed rule at 80 FR 2889-2890; January 21, 2015

E. What are the potential health and environmental effects of LCPFAC chemical substances?

The following brief summary of chemistry, environmental fate, exposure pathways, and health and environmental effects of LCPFAC chemical substances is based on the 2009 Action Plan (Ref. 1), references cited in the 2009 Action Plan, and additional selected references published after the 2009 Action Plan.

PFOA is persistent, widely present in humans and the environment, has long half-lives in humans, and can cause adverse effects in laboratory animals, including cancer and developmental and systemic toxicity (Refs. 11, 12, 13, 14, and 15). PFOA precursors, chemicals which degrade or may degrade to PFOA, are also present worldwide in humans and the environment and, in some cases, might be present at higher concentrations than PFOA and be more toxic (Refs. 16, 17, 18, 19, and 20). PFOA higher homologues are chemicals with carbon chain lengths longer than PFOA. Available evidence suggests that toxicity and bioaccumulation appear to be higher for chemical substances with longer carbon chain lengths compared to those with shorter chain lengths (Refs. 21, 22, 23, and 24).

LCPFAC chemical substances have been detected in biota, air, water, dust, and soil samples collected throughout the world. Some LCPFAC chemical substances have the potential for long-range transport. They are transported over long distances by a combination of dissolved-phase ocean and gas-phase atmospheric transport; however, determining which is the predominant transport pathway is complicated by many factors, including the uncertainty over water to atmosphere partitioning. Furthermore, there is evidence that transport and subsequent oxidation of volatile alcohol LCPFAC chemical substance precursors contribute to the levels of LCPFAC chemical substances in the environment.

For a more detailed summary of background information (e.g., chemistry, environmental fate, exposure pathways, and health and environmental effects), as well as references pertaining to LCPFAC chemical substances, please refer to Unit IV. of EPA's initial proposed SNUR on LCPFAC chemical substances published in the Federal Register of August 15, 2012 (Ref. 10).

#### F. What are the potential health and environmental effects of PFAS chemical substances?

PFAS chemical substances degrade ultimately to perfluoroalkylsulfonic acid (PFASA), which can exist in the anionic form under environmental conditions. Further degradation of PFASA is not observed under normal environmental conditions. PFASA is highly persistent in the environment and has a tendency to bioaccumulate (Ref. 25). PFASA can continue to be formed by any PFAS containing chemical substances introduced into the environment.

Studies have found PFAS chemical substances containing 5 to 14 carbons (C5-C14) in the blood of the general human population as well as in wildlife, indicating that exposure to these chemical substances is widespread (Refs. 1, 4, 26, 27, 28, and 29). The widespread presence of PFAS chemical substances in human blood samples nationwide suggests other pathways of exposure, possibly including the release of PFAS from treated articles.

Biological sampling has shown the presence of certain perfluoroalkyl compounds in fish and in fish-eating birds across the United States and in locations in Canada, Sweden, and the South Pacific (Refs. 26 and 27). The wide distribution of the chemical substances in high trophic levels is strongly suggestive of the potential for bioaccumulation and/or bioconcentration.

Based on currently available information, EPA believes that while all PFAS chemical substances are expected to persist, the length of the perfluorinated chain may also have an effect on bioaccumulation and toxicity, which are also characteristics of concern for these chemical substances. PFAS chemical substances with longer carbon chain lengths may be of greater concern than those with shorter chain lengths (Refs. 4, 21, and 22).

The hazard assessment published by the Organization for Economic Cooperation and Development (Ref. 10) concluded that perfluorooctyl sulfonates (PFOS) are persistent, bioaccumulative and toxic to mammalian species. While most studies to date have focused primarily on PFOS, structure-activity relationship analysis indicates that the results of those studies are applicable to the entire category of PFAS chemical substances, which includes PFOS. Available test data have raised concerns about their potential developmental, reproductive, and systemic toxicity (Refs. 1, 16, 26, and 27).

For a more detailed summary of background information (e.g., chemistry, environmental fate, exposure pathways, and health and environmental effects), as well as references pertaining to PFAS chemical substances, please refer to EPA's proposed SNURs on PFAS chemical substances published in the Federal Register of October 18, 2000 (Ref. 30), March 11, 2002, and March 10, 2006 (Refs. 26 and 31). Also, refer to the 2009 Action Plan (Ref. 1).

## Chemical Data Reporting (CDR) Inorganic Byproducts Meeting

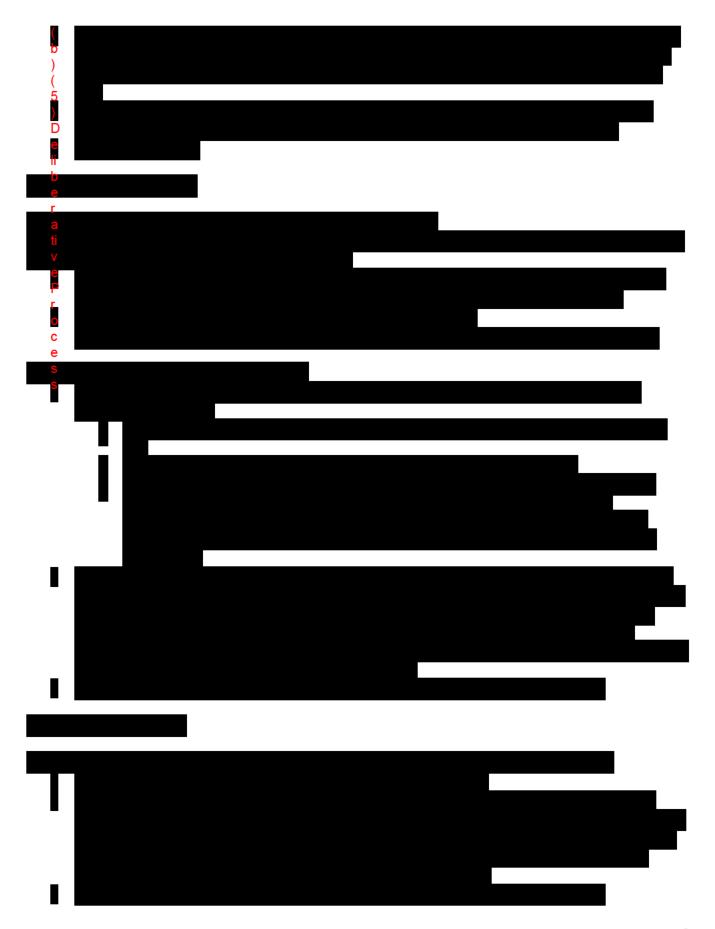
June 8-9th, 2017

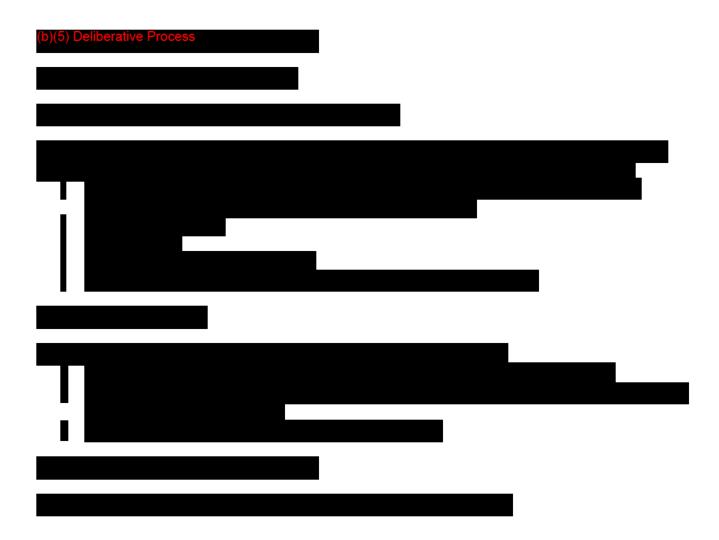
U.S. Environmental Protection Agency William Jefferson Clinton East Building, Room 1153 1201 Constitution Avenue NW, Washington, DC

(Enter at the NW corner of Constitution Avenue and 12th Street NW)

### Draft Agenda (As of 5/22/17)







Internal – Deliberative May 23, 2017

#### CDR Inorganic Byproducts: Notices and Schedule Milestones

- Statutory deadlines:
  - o 3 years for proposal (June 2019)
  - o 6 months following that for finalization (December 2019)
- Next CDR submission period: June September 2020

#### Overview of Proposed Rule Schedule (Tier 3)



Internal – Deliberative May 11, 2017

# Summary of Chemical Data Reporting (CDR) Inorganic Byproducts Negotiating Committee: May Organizational Planning Meeting

On May 9 – 10, 2017, EPA held a public meeting with prospective members of the committee to negotiate a proposed rule providing for limiting chemical data reporting requirements under subsection 8(a) of the Toxic Substances Control Act (TSCA), for manufacturers of any inorganic byproducts, when such byproducts are subsequently recycled, reused, or reprocessed. This negotiation process is required by TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The objective of the negotiated rulemaking process is to develop and publish a proposed rule by the statutory deadline of June 22, 2019.

Under the TSCA Section 8(a) Chemical Data Reporting (CDR) rule, EPA collects data from manufacturers (including importers) on the manufacturing, processing, and use of chemical substances in commerce, for those chemical substances listed on the TSCA Inventory.

#### Purpose of the Organizational Meeting held on May 9-10, 2017

• For EPA to convene with prospective committee members and the public to exchange information and to discuss the process of negotiated rulemaking. Meeting agenda is attached.

#### Who Attended

- Prospective members:
  - o Inorganic chemical manufacturers and processors, including metal mining and printed circuit board manufacturers; recyclers, including scrap recyclers; and industry advocacy groups
  - o Environmental advocacy groups; State and Tribal government representatives
  - o EPA prospective committee members (2) and advisors from OCSPP, OGC, OECA, OLEM, and OP
- Other members of the public or other Agencies
  - o Small Business Administration (2 representatives)
  - Members of the public affiliated with prospective members

#### **Key Messages from the Meeting**

- Participants were very engaged. More than 30 prospective members actively participated in the two-day meeting.
- EPA and industry presentations generated significant discussion, including identification of substantive topics for discussion at the next meeting.
- Discussions related to CDR reporting included:
  - Prospective members' interest that EPA receive useful and accurate information under CDR. Participants
    were interested in gaining a better understanding of how the data are used and why it is needed in low-risk
    scenarios.
  - O When reporting to CDR, how to properly identify inorganic byproducts when they are hard to identify to the level of granularity that TSCA 8(a) requires. For example, RCRA allows wastewater treatment sludge to be reported as F006; whereas TRI allows identification of copper or copper compounds but TSCA requires identification of inventory-listed chemical substances or a UVCB. Industry is reluctant to go through the PMN process for a byproduct UVCB.
  - Request that the byproduct exemption be further explored to determine if the current exemption could be expanded to include all types of recycling.
- Because this was an organizational meeting, substantial discussion also included procedures for how the Committee would operate. Some participants had concerns that the use of unanimous consensus could result in one individual blocking a successful effort; this was identified as an issue for further discussion.
- Issues outside the scope will be diverted to the CDR Revisions rule, which is under development and planned to be proposed and finalized for the next CDR submission period in 2020.

#### Steps required to hold the first FACA meeting on June 7-8, 2017

- Approval from the Deputy Administrator on the Charter and Membership Package (currently at the OA)
- Publishing of the Federal Register Notice for the first FACA committee meeting (2<sup>nd</sup> public meeting)

Attached: Agenda from May meeting and Membership Grid (part of the Membership Package)

#### Selection Process for Proposed CDR Reg Neg Committee Membership:

- In Initial FR Notice of 12/15/16, EPA initially identified representative interests likely to be significantly affected by a rule:
  - These were industries that had previously contacted us about the byproduct report issue as well as environmental organizations
  - In the FR EPA took comment regarding our tentative list as well as asked those who
    were interested in being appointed to the Negotiated Rulemaking Committee to submit
    comments to this affect till 1/16/17.
- The Negotiated Rule-Making Facilitators, who are under contract to EPA's Conflict Prevention and Resolution Center, then interviewed all of the potential interests by early February.
- The results of these interviews, which also included a solicitation of potential topics for the Negotiated Rulemaking, were compiled into a Situation Assessment Report (SAR).
- CCD reviewed the process, membership and Situation Assessment Report with OPPT and OSCPP
   IO management in February
- The SAR explains that there are two representatives rather than one for each stakeholder group because:
  - Given the technical nature of the deliberations, we aimed to maximize knowledge by having two representatives and preferably a technical/policy combination (e.g. trade association rep and industry company rep).
  - Given the fast nature of the deliberations, we didn't want any one stakeholder group to miss a meeting, thus there would always be a substitute.
- As guided by EPA's FACA office, the membership package was sent to FACAMD for processing thru to the Deputy Administrator for formal approval
- Once DA approves members, the OCSPP AA will sign the transmittal memo that will start the formal process of alerting the prospective members to their new FACA status.

#### **Solvent Strategy**

The solvent strategy is designed to more comprehensively look at chemicals that are substitutes for each other. It was developed following stakeholders' requests to be better prepared to plan for substitution or process changes as a result of regulatory action.

This document presents a strategy to address risks presented by solvents while also identifying substitutes that:

- Are technically and economically feasible alternatives
- Reduce overall risk to human health and the environment
- Prevent the issue of regrettable substitutions

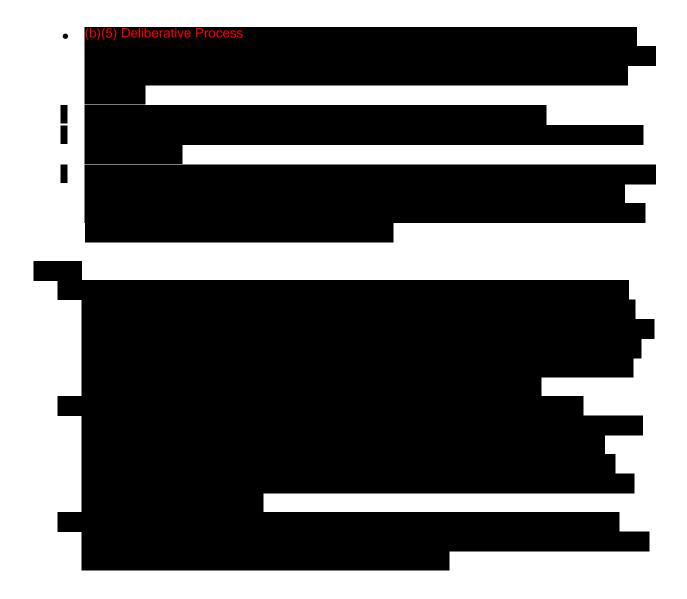
The design of the strategy can apply more broadly to groups of chemicals beyond solvents e.g. flame retardants.

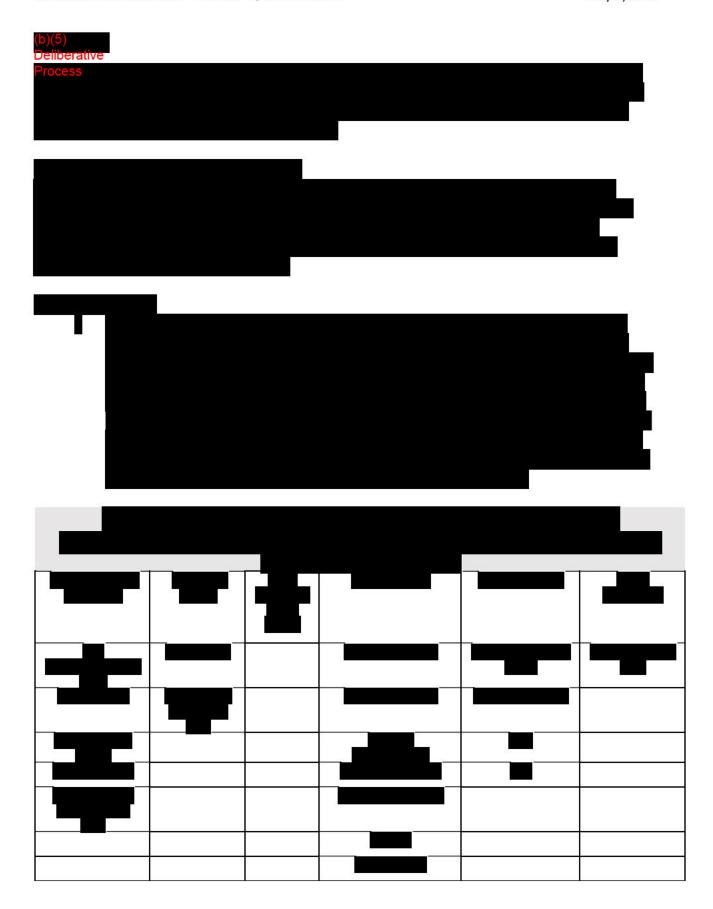
The strategy has three main elements:

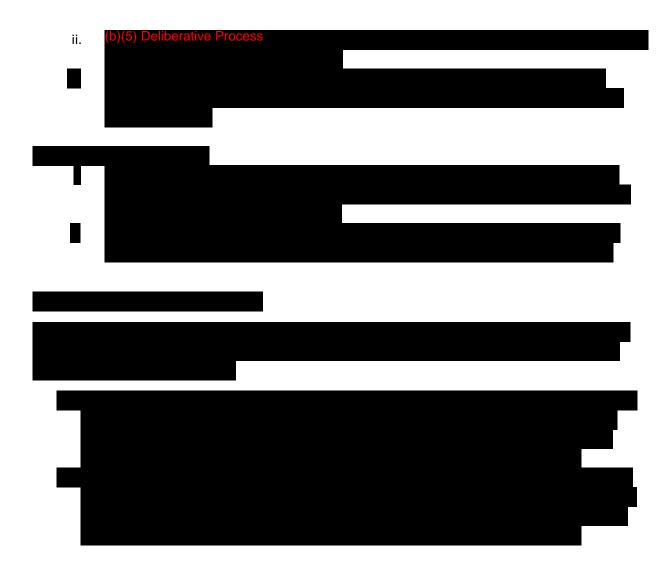












# CPMA Meeting with Brittany Bolen, Deputy Associate Administrator for Policy

**USEPA HQ** 

Wednesday, June 7, 2017

1:00-1:30 PM



# Meeting Agenda

- Introductions
- Color pigments industry overview John Marten, CPMA President
- CPMA overview David Wawer, CPMA Executive Director
- Key EPA issues for CPMA:
  - Level playing field and fairness
  - Efficiency of EPA staff
  - NGO's influence
  - Regional office overreach/conflicts with state environmental agencies
- EPA strategic policy objectives Brittany Bolen
- Potential areas of collaboration; other next steps
- Adjournment



#### TSCA Section 6(a) Rules: Methylene Chloride Furniture Refinishing (Proposed)

- Paint Removers NPRM: Proposed regulation of methylene chloride in most commercial and all consumer
  paint and coating removal, and NMP in all paint and coating removal.
  - Published January 2017. Comment period closed May 2017.
  - Public comments under review, with a focus on comments that relate to furniture refinishing
- Commercial Furniture Refinishing with Methylene Chloride:
  - In the Paint Removers NPRM, EPA identified unreasonable risks for paint and coating removal with methylene chloride in commercial furniture refinishing, but explained that restrictions could not be proposed at that time due to lack of information on the economic impacts of proposed regulations.
  - A section of the NPRM identified next steps regarding proposed regulations on methylene chloride in commercial furniture refinishing:
    - "EPA plans to hold a series of stakeholder meetings. These meetings will focus on current practices related to methylene chloride for paint and coating removal in commercial furniture refinishing; any substitute chemicals or alternative methods currently in use or under development; and current and best practices related to respiratory protection programs and exposure reduction." (Jan 19 82 FR 7497)
    - "EPA views this section as an advanced notice of proposed rulemaking, and intends to issue a notice of proposed rulemaking following a series of stakeholder meetings and further analysis on the cost impacts of regulatory action on this industry. Following that proposal and public comment period, EPA intends to finalize together the regulations proposed and the future proposal related to methylene chloride in furniture refinishing." (Jan 19 82 FR 7498)



#### TSCA Section 6(a) Rules: TCE (final)

#### TCE NPRMs:

- Spot cleaning and aerosol degreasing published December 2016; comment period closed March 2017
   (22 comments)
- Vapor degreasing published January 2017; comment period closed May 2017 (~500 comments)
- Notable Comments (TCE1): In general, non-industry commenters supported the rule. Industry and trade
  organizations had adverse comments and argued that EPA should withdraw the proposed rule and
  reassess the TCE uses in this rule as part of its ongoing risk evaluation of TCE. Most notable comments
  are listed below.
  - The risk management decision extends beyond the scope of the corresponding risk assessment and therefore lacks proper scientific support.
  - EPA should not use the Johnson et al. study on cardiac malformation.
  - o Spot cleaning in dry cleaning was included in the final risk assessment without peer review.
  - Supplemental analyses on occupational exposure for TCE use in aerosol degreasing and exposure assessment for TCE in spot cleaning at dry cleaning facilities have not been peer reviewed.
  - EPA should also reassess the impacts of the rule on small businesses and convene a SBREFA panel for aerosol degreasing and spot cleaning at dry cleaning facilities.
  - Critical uses (such as energized electrical cleaners) for aerosol degreasing should be allowed.
  - EPA's analysis does not account for additional steps needed when using alternative products nor the feasibility of the alternatives in some processes.
  - EPA should reconsider whether the unreasonable risks identified in the rulemaking "may be prevented or reduced to a sufficient extent" by OSHA and CPSC.





# REGULATING PESTICIDE USE ON CANNABIS JUNE 15, 2017

#### ISSUE

Develop EPA's position regarding appropriate pesticide use for cannabis<sup>1</sup> and related state requests. Specific issue to address is: 1) the Special Local Needs registrations in three states.

#### BACKGROUND

- Many states have legalized cannabis for medical and recreational use, yet cannabis remains a schedule I controlled substance under federal law.
- There are no pesticides registered by EPA specifically for use on marijuana; however, some pesticide labels do list industrial hemp among the crops. The lack of registered pesticides for use on cannabis poses pest control challenges and potential and unknown human health concerns where pesticides are illegally used on cannabis plants that are later inhaled, applied dermally and/or ingested. Human health risk assessments, including dietary and occupational assessments, required to register pesticides have not been conducted for cannabis.
- Some states have taken the position that certain registered pesticides that contain broad use directions (i.e., "may be used on bedding plants") may be used on cannabis.
   Additionally, several states have published lists of pesticide products with such broad label language and made those lists available to their cannabis producers.
- Also, pesticides that are exempt from federal registration requirements under section 25(b) can be used on cannabis without violating FIFRA.
- Some states have passed legislation which directly (identify specific pesticides) or indirectly (setting tolerances for pesticides) allows the use of pesticides on cannabis within their state, in a manner that is inconsistent with FIFRA. The use of certain pesticides on cannabis is a violation of FIFRA. However, most states have primary enforcement responsibility (primacy) for pesticide use violations as long as the state pesticide use laws are consistent with FIFRA.

<sup>&</sup>lt;sup>1</sup> For the purposes of this document, the Agency is using the following draft definitions.

Cannabis: Plants in the genus Cannabis that are grown for production purposes. Includes both "marijuana" and "hemp" as defined below. Both forms are controlled substances under the Controlled Substances Act.

Marijuana: Cannabis plants (Cannabis sativa L. or Cannabis indica) and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol [THC] concentration of more than 0.3 percent on a dry weight basis. Hemp: The plant Cannabis sativa L. and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol [THC] concentration of not more than 0.3 percent on a dry weight basis. Also referred to as "industrial hemp." USDA further defines industrial hemp as "including seeds of such plant, whether growing or not, that is used exclusively for industrial purposes (fiber and seed)" and defines tetrahydrocannabinols as "all isomers, acids, salts, and salts of isomers of tetrahydrocannabinols" (Federal Register, Vol. 81, No. 156, page 53395-53396).

- The Office of Pesticide Programs (OPP) is responsible for the registration of pesticides and the Office of Enforcement and Compliance Assurance (OECA) oversees the cooperative agreement program that confers primacy to the states for pesticide use.
- Most states have cooperative agreements with EPA and primacy to enforce pesticide use violations. There are, however, statutory and regulatory requirements that must be met in order for EPA to confer primacy:
  - Where primacy is obtained via: (1) an EPA primacy determination; or (2) an approved certification program, FIFRA requires that states must have adequate pesticide use laws/regulations and adequate procedures implementing those laws (FIFRA Section 26(a) and (b)).
  - Where primacy is obtained via a cooperative agreement, the adequacy criteria are not expressly required by statute (FIFRA Section 26(b)). However, the Agency's Final Interpretive Rule (48 FR 404-411, January 5, 1983) requires EPA to conduct an evaluation using the adequacy criteria in Section 26(a) before conferring primacy via cooperative agreement.
- OPP, OECA, OGC, and the Regions have worked together on issues pertaining to the regulation of pesticide use on cannabis.

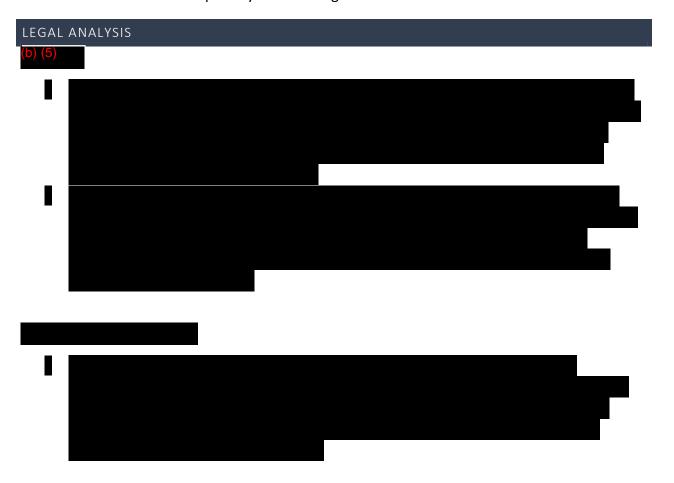


- o EPA is also coordinating with DOJ and FDA.
- As the number of states and tribes who have legalized medical and/or recreational cannabis grows<sup>2</sup>, the need is growing for the agency to take positions on the use of pesticides on cannabis:
  - Cannabis growers have significant issues with pests, most notably spider mites, aphids, and powdery mildew and other molds. Unregistered pesticides in cannabis production are used to improve yield and profits for growers. Illegal residues of insecticides/miticides and fungicides have been found on cannabis being grown for both medical and recreational uses. These pesticides have

2

<sup>&</sup>lt;sup>2</sup> Eight states and the District of Columbia have legalized both recreational and medical marijuana; other states have decriminalized marijuana. Three tribes have legalized marijuana. Another 28 states, Guam and Puerto Rico have medical marijuana only (includes 14 states with CBD-only programs). In 2017, over 30 states will consider legislation related to cannabis, approximately half of those bills are for legalization of medical or recreational marijuana.

- unknown health consequences when used on cannabis, and may pose serious risks to public health.
- Recently, OPP received applications for "special local needs" registrations from three states: Nevada, Vermont, and Washington.
  - Each state issued four 24(c) registrations on April 4, 2017.
  - The products contain the pesticide active ingredients Capsicum oleoresin extract, garlic oil, & soybean oil; Bacillus amyloliquefaciens strain D747; Azadirachtin; and Potassium salts of fatty acids
  - Section 24(c) provisions provide that use could begin immediately and while the agency considers the registrations.
  - OPP conducted a baseline review of these actions and found that no human health or ecological risk issues of concern were identified.
- States have been inquiring about whether additional products could be considered under FIFRA 24(c).
- Recently, there had been pending Colorado state legislation, which would have allowed the use of certain pesticides on marijuana in Colorado despite there being no pesticides currently registered by EPA, potentially at odds with FIFRA and state primacy requirements. Ultimately, the pesticide-related provisions were not adopted by the state legislature.





#### ACTION ITEM

#### **Special Local Needs Options**



# Update on ESA Pesticide Consultations

# Background: Endangered Species Act (ESA) Obligations for Pesticide Decisions

- Why are pesticide decisions impacted by the ESA?
  - Under Section 7(a)(2) of the ESA, Federal agencies must ensure that the
     "actions" they authorize will not result in jeopardy or adversely modify
     designated critical habitat for species listed as endangered or threatened by
     the U.S. Fish and Wildlife Service (FWS) and/or the National Marine Fisheries
     Service (NMFS) (jointly the Services)
  - For EPA's Office of Pesticide Programs (OPP), the actions we authorize are the sale, distribution, and use of pesticides according to the product labeling
- Conventional pesticide decisions impacted by ESA:
  - Registration review actions (~50-60/yr)
  - New chemical registrations (~10-12/yr)
  - New use registrations (~50-60/yr)
  - Section 18 Emergency Exemptions (~100/yr)
  - Section 24(c) Special Local Need (SLN) registrations (~200/yr)

# Background

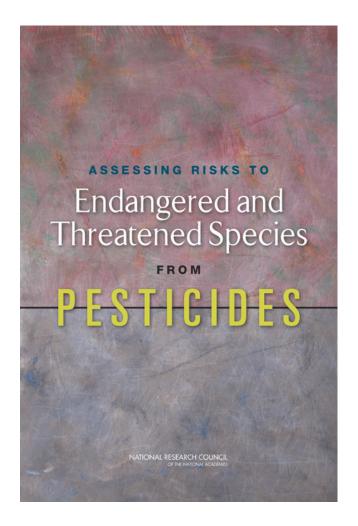
- ESA Authority
  - Section 7(a)(2) of ESA: EPA makes "effects determination" for individual listed species in a biological evaluation (BE):
    - No effect (NE) no consultation required
      - Overview Document-compliant method (2004): Risk Quotient (RQ) < listed species Level of Concern (LOC)
      - NAS-recommended method (2013): No geospatial co-occurrence of pesticide use footprint with listed species range
    - Not likely to adversely affect (NLAA) informal consultation; concurrence from Services
    - Likely to adversely affect (LAA) formal consultation including Biological Opinion (BiOp) from Services (jeopardy/no jeopardy determination)
- Nationwide consultations must consider direct/indirect effects to 1850 listed species and 600+ designated critical habitats

## Background - OPP History with the Services

(b)(5) Deliberative Process

- EPA has completed over 200 chemical-specific BEs as the result of court-imposed ESA obligations. The Services have issued 9 BiOps based on court-mandated schedules. None of these BEs or BiOps were nationwide evaluations.
- Of 7 BiOps for listed Pacific Northwest salmon species submitted by NMFS (covering 32 chemicals), EPA has implemented only one (thiobencarb); NMFS 1<sup>st</sup> BiOp was overturned.
  - Reasonable and Prudent Alternatives (RPAs)/Reasonable and Prudent Measures (RPMs) not feasible/practical to implement:
    - Arbitrary spray drift buffers
    - Lack of a target concentration where effects to listed salmon do not cause jeopardy
- EPA has implemented 2 BiOps submitted by FWS for Rozol and Kaput rodenticides
  - Geographically-specific Bulletins which restrict product use or timing of application

### **NAS** Report Implementation



- Released on April 30, 2013
- Developed in response to a joint request by EPA, NMFS, FWS, and USDA in 2011 to address scientific areas of disagreement
- Recommended 3-step process that integrates ecological risk assessment methods with ESA Section 7 consultations
- Goal: unified interagency approach with agreement on process across all steps
- Multiple interagency workshops where interim methods for EPA's BEs (Steps 1 and 2) have been developed
- Several stakeholder meetings held to engage public on potential refinements
- Interim methods need streamlining to meet available resources
- Final BEs for chlorpyrifos, diazinon, and malathion released in January 2017

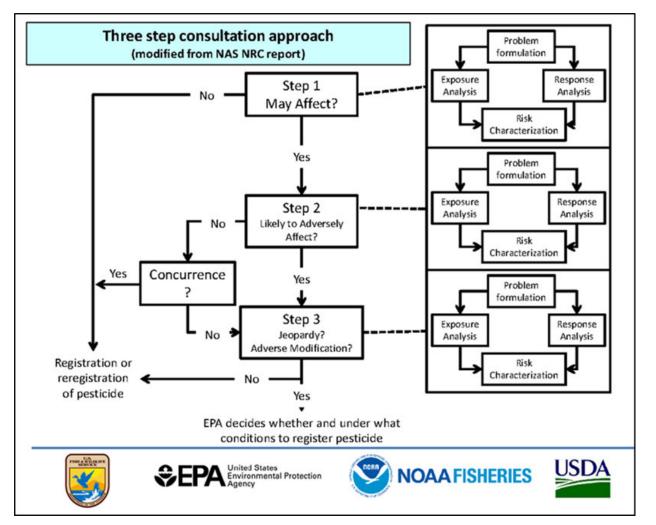
## **NAS Report Implementation**

- The <u>Biological Evaluation</u> (BE) determines whether registered pesticides adversely affect one or more individuals of a listed species and/or their designated critical habitats
  - Step 1 ["No Effect/May Affect" Determination]
  - Step 2 ["Not Likely to Adversely Affect (NLAA)/Likely to Adversely Affect (LAA)
     Determination]
- The <u>Biological Opinion</u> (BiOp) determines whether the registration of a pesticide is likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of its designated critical habitat
  - Step 3 ["Jeopardy/No Jeopardy" Determination and "Adverse Modification/No Adverse Modification" Determination]



## Methodology for Pesticide Consultations

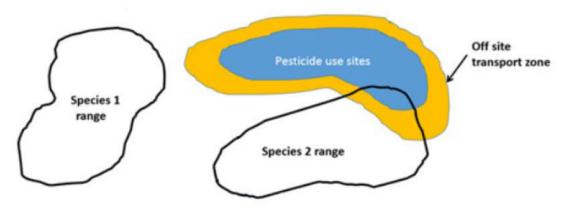
The draft process follows the 2013 NAS recommendations for a 3-step approach:



The draft BE process was developed in close coordination with the Services – EPA has worked very hard to provide information in Steps 1 and 2 that the Services said they would need to conduct Step 3.

## Overview of the BE Method – Step 1

- Two sets of spatial data are compared
  - Pesticide exposure area
    - Based on national-level GIS data to identify potential use sites
    - Buffered to account for transport to levels that potentially represent effects (based on most sensitive toxicity data)
  - Species range provided by Services
- No Effect /May Affect determination
  - Based on whether or not there is overlap of the potential exposure area and the species range
    - No Effect (i.e., no overlap) no need to seek consultation with Services
    - May Affect (i.e., overlap) move to step 2



## Overview of the BE Method –Step 2

- Step 2
  - Weight-of-Evidence Approach
    - Risk and confidence evaluated for multiple lines of evidence (mortality, growth, reproduction and other sublethal effects) based on estimated exposure and effects thresholds
    - Incident data
    - Qualitative discussion of mixtures and abiotic influence (e.g., temperature, pH) on toxicity
- Intended to answer the questions:
  - Is there a potential for an individual's fitness to be reduced?
  - Is there a potential for important physical and biological features of a species habitat to be adversely affected?
- Describes the process for making Likely to Adversely Affect(LAA)/Not Likely to Adversely Affect (NLAA) Determinations
  - LAA species/critical habitat moves to Step 3 (jeopardy/adverse modification determination)
  - NLAA concurrence from the Services

## Step 3 – Services BiOps

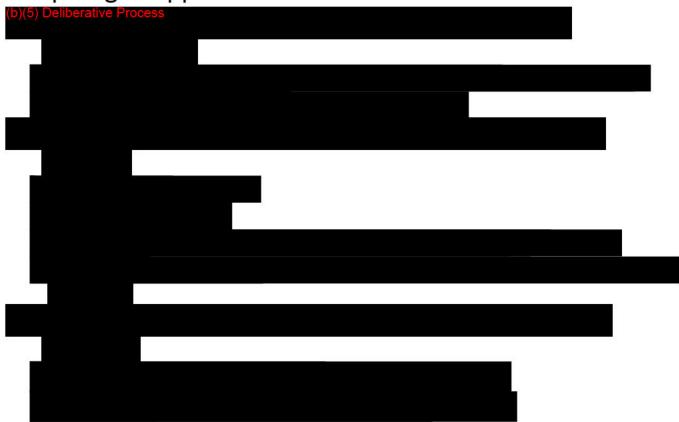
- Services are currently working on BiOps (Step 3) for chlorpyrifos, diazinon and malathion
  - Proposed delivery date of June 30, 2017 to EPA
- EPA and Services have had several workshops discussing the methodology for population-level risk assessments of endangered species
  - To date, an interagency method has not been reached
  - EPA has provided comments on specific sections of the BiOps to the Services
  - EPA has developed the MAG tool to facilitate analysis of large amounts of data generated in the BEs for the population level risk assessments

## Litigation and Settlement Agreements

- Settlement agreements on ESA-litigation
  - Grand Bargain resolved 4 cases to allow agencies to focus ESA compliance and NAS report implementation on nationwide effects determinations and BiOps for 5 pesticides (chlorpyrifos, diazinon, malathion, carbaryl, and methomyl)
    - Final BiOps for chlorpyrifos, diazinon and malathion due in Dec. 2017
    - Final BiOps for carbaryl and methomyl due in Dec. 2018
- EPA and FWS resolved 2 cases with Center for Biological Diversity (CBD) to set schedules for next 4 nationwide pesticide consultations (atrazine, glyphosate, simazine, and propazine)
  - EPA to complete final BEs in June 2020
  - FWS to complete final BiOps in June 2022
- Ongoing ESA challenges:
  - New chemical registrations (cyantraniliprole, flupyridifurone, bicyclopyrone, benzovindiflupyr, and one antimicrobial chemical (coupron couprous iodide)
  - Ellis v. Housenger (clothianidin and thiamethoxam)
  - Megasuit

# **OPP Approach for ESA Compliance**

• Three-pronged approach:



### **BE Conclusions**

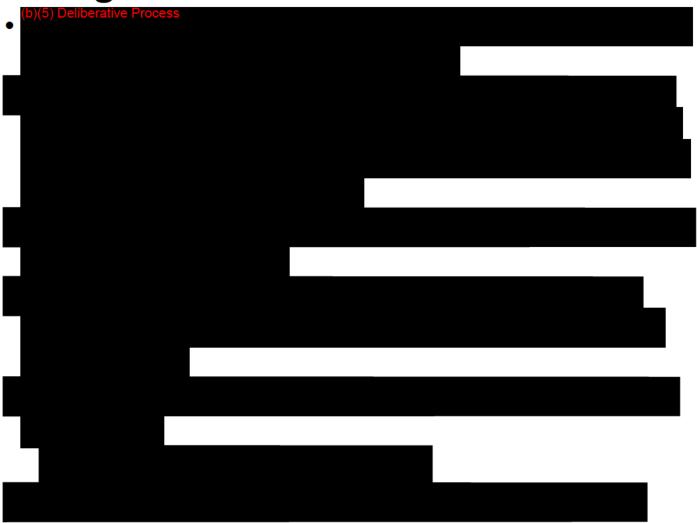
- LAA for most listed species
  - Chlorpyrifos and malathion 97% LAA
  - Diazinon ~80% LAA
  - Due to overlap of range/critical habitat and potential uses sites
  - Low thresholds (high toxicity), maximum use rates, other assumptions of exposure
  - Weight-of-evidence approach
  - LAA for <u>single individual</u> of a listed species



### Stakeholder Concerns

- April 13, 2017 letter from registrants of 3 pilot OPs to political leadership of EPA and the Services requesting:
  - EPA to withdraw the BEs
  - Services to stop work on the BiOps
  - Services to modify settlement agreements to allow more time to complete consultation
- Registrants/Growers:
  - Too large and complex; inadequate comment period
  - Current methods are not sustainable
  - Do not account for taxon-specific toxicity data early enough in the process
  - Overly conservative
  - GIS layers used are too broad (for use site and species range layers)
  - Use of invalid and un-reviewed studies
  - Need to consider public health, usage data and benefits
- NGOs
  - Too large and complex
  - Generally agreed with the overall process

# Challenges



# **Next Steps: Future Consultations**





## Background: ESA Timeline

- April 2013 NAS report issued
- November 2013 release of interim scientific methods for implementing NAS recommendations
- April 2016 First draft BEs posted for public comment (chlorpyrifos, malathion, and diazinon)
- June 2016 2-day stakeholder workshop
- September 2016 to present Interagency workshops on BO process
- September 2016 Stakeholder meeting on mosquitocides uses
- January 2017 Final BEs for chlorpyrifos, malathion, and diazinon
- April 2017 Industry requests current pesticide consultations be put on hold

# **Update on Endangered Species Act Pesticide Consultations Meeting Agenda – June 19, 2017**

- Introductions
- Brief Background and History of ESA Related Issues
- National Academy of Sciences Report Implementation
- Litigation and Settlement Agreements
- Stakeholder Concerns
- Challenges
- Group Discussion
- Timeline
- Next Steps







### Safer Chemical Ingredients List (SCIL)

Briefing- July 26, 2017

epa.gov/saferchoice

# Outline: Presentation on the Safer Chemical Ingredients List (SCIL)



- Context for SCIL
- Public interface for SCIL
- Safer Choice criteria for listing on SCIL
- Uses of SCIL

### Safer Choice-Certified Products



- About 2,000 labeled products from 500 American manufacturing partners
  - ~ **700** Retail
  - >1,300 Industrial & Institutional
- A majority of partners are small businesses
- Participating chemical manufacturers include:
  - AkzoNobel, BASF, Dow, Eastman, Milliken, Novozymes, Rivertop Renewables, Stepan

# Safer Chemical Ingredients List

Show 25 V entries



#### Safer Chemical Ingredients List

- The listed chemicals are safer alternatives, grouped by their <u>functional-use class</u>.<sup>†</sup>
- Chemicals are marked as a 
   <sup>Q</sup> green circle, 
   <sup>Q</sup> green half-circle, 
   <sup>Q</sup> yellow triangle, or 
   <sup>Q</sup> grey square.<sup>‡</sup>
- This list includes many of the chemicals evaluated through the Safer Choice Program. It does not include
  confidential chemicals. There may be chemicals not included in this list that are also safer.
- Some of the listed chemicals may not be on the <u>TSCA inventory</u> and therefore may not be authorized/allowed
  for TSCA uses. Those considering TSCA uses for these chemicals should first determine whether such use is
  authorized. Chemicals not listed on the TSCA inventory are indicated as such in a pop-up box that appears
  upon clicking the hyperlinked CAS RN in the table below.

# www.epa.gov/saferchoice/safer-ingredients

 Chemicals searchable by Name and CAS RN

**Clear Options** 

#### ♦ Please Select: All Functional Use Classes

#### or Select a Functional Use Class:

- Antimicrobial Actives
- Chelating Agents
- Colorants
- Defoamers
- Emollients
- Enzymes and Enzyme Stabilizers
- Fragrances
- Oxidants and Oxidant Stabilizers
- Polymers
- Preservatives and Antioxidants
- Processing Aids and Additives
- Skin Conditioning Agents
- Solvents

#### **Chelating Agents**

Note: When a functional use category is selected, the search above will only apply to the chemicals assigned to this functional use. To select a different functional use, please <a href="scroll-up">scroll-up</a>.

Code	<b>♦</b> Common Name	CAS Registry Number	<b>♦ Functional Use</b>
0	2-Butenedioic acid (2Z)-, ammonium salt (1:?), homopolymer, hydrolyzed, sodium salts	181828-06-8	Chelating Agents
•	Alanine, N,N-bis(carboxymethyl)-, sodium salt (1:3)	<u>164462-16-2</u>	Chelating Agents
	Aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt	144538-83-0	Chelating Agents
•	Citric acid, anhydrous	77-92-9	Antimicrobial Actives; Chelating Agents; Processing Aids and Additives
•	D-Gluconic acid	<u>526-95-4</u>	Chelating Agents; Processing Aids and Additives



Safer Choice Program

# Safer Chemical Ingredient List Color Codes



- Green circle low hazard based on experimental or modeled data.
- Green half-circle expected to be of low hazard based on experimental or modeled data. Additional data would strengthen our confidence in the chemical's status
- Yellow triangle met Safer Choice Criteria for its functional ingredient class, but has some hazard profile issues.

# Safer Chemical Ingredients List



870 chemicals & 929 listings on SCIL as of July 2017

#### By functional ingredient classes:

- -Antimicrobial Actives (7)
- -Chelating Agents (20)
- -Colorants (44)
- -Defoamers (12)
- -Emollients (18)
- -Enzymes & Enzyme Stabilizers (26)
- -Fragrances (156)
- -Oxidant & Oxidant Stabilizers (18)
- -Polymers (58)

- -Preservatives & Antioxidants (32)
- -Processing Aids & Additives (130)
- -Skin Conditioning Agents- (27)
- -Solvents (67)
- -Specialized Industrial Chemicals (14)
- -Surfactants (276)
- -Uncategorized (24)



### **How Chemicals are Listed on SCIL**



- A SCIL listing can be initiated by:
  - Product manufacturer using a new-to-Safer Choice chemical in a formulation
  - Chemical manufacturer who would like to have one of their products listed on SCIL
  - EPA identifying chemicals meeting the criteria
- Steps for a product or chemical manufacturer to list:
  - The manufacturer could request a Safer Choice-qualified third party to prepare a dossier
  - Safer Choice review and verification
- Chemicals that meet Safer Choice criteria are listed on SCIL



# Toxicological Endpoints Included in the Criteria



### **Human Health Toxicity**

- Acute mammalian toxicity
- Repeated dose toxicity
- Carcinogenicity
- Mutagenicity/ Genotoxicity
- Reproductive and developmental toxicity
- Neurotoxicity
- Respiratory and skin sensitization
- Eye and skin irritation/ corrosivity

# **Environmental Fate & Effects**

- Aquatic toxicity
- Environmental persistence
- Bioaccumulation

### **Endocrine Activity**

Considered, but related to traditional endpoints



# Requirements for SCIL Listing



#### **Criteria**

- Aligned with low concern thresholds under the TSCA New Chemicals program
- Supplemented with thresholds from GHS

### Data requirements vary by functional class; examples:

 Surfactants are differentiated based largely on aquatic toxicity and rate of biodegradation

# Acute Mammalian Toxicity Criteria Example



- To be listed on SCIL and used in Safer Choice products, chemicals must meet the criteria
- For acute mammalian toxicity, data must demonstrate that chemical toxicity thresholds are above cutoff values

Route (units)	Median Lethal Dose/Concentration	
Oral, LD50 (mg/kg bw)	2,000	
Dermal, LD50 (mg/kg bw)	2,000	
Inhalation, LC50 (vapor/gas) (mg/L)	20	
Inhalation, LC50 (dust/mist/fumes) (mg/L)	5	

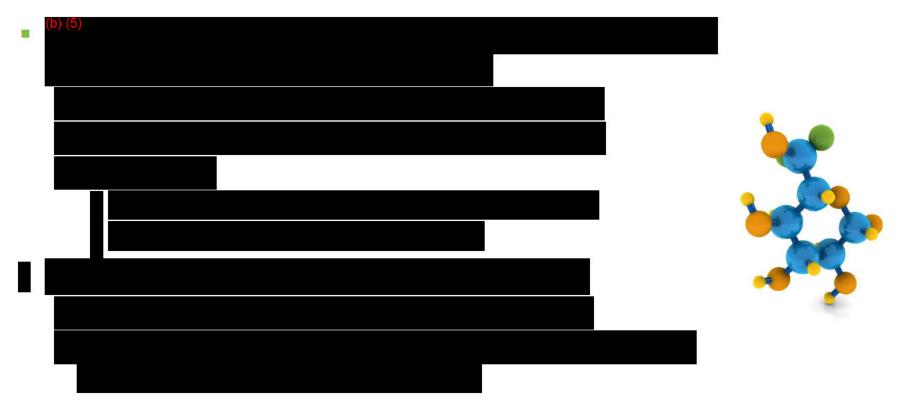
# **Toxicological Data Hierarchy**



- Experimental data
- Analog data
- Modeled data (i.e. ECOSAR, EPISuite)
- EPA technical workgroup makes the call on SCIL listing, modeled on the new chemicals process
  - Chemists, toxicologists, others

## **Uses of SCIL**





## Identifying the strongest candidates



Total SCIL chemicals:	~ 850
Half green or yellow triangle	- 300
CAS numbers with variable composition	- 200
Chemicals listed under criteria that do not require a full dataset	- 250
Chemicals not in a fielded database	- 50
Chemicals with robust data set in a fielded data system	= 50



## 50 remaining SCIL chemicals



- Currently manufactured
- Discrete substance
- Full hazard data set
  - Empirical data for the chemical,
  - Data for a good analog, or
  - Modeling.
- Data recent and available in one modern system

## Thank you!



## Questions on SCIL?







## **Detergent Packets**

Safer Choice Program Briefing- July 26, 2017

epa.gov/saferchoice

## **Detergent Packet Issues**



- Fastest-growing segment of laundry detergent market
- Potential hazard to young children and the mentally impaired
- A number of poisoning incidents and fatalities, disproportionate to non-packet products



### Decision to Exit Sector in Dec. 2016



- No new partnerships and sunset of two existing partnerships
  - Cot'n Wash (consumer)
  - Aqua ChemPacs (institutional)
- Companies notified orally and policy posted on website
  - Written notice not provided to the two companies
- Sunset date set six months hence—June 30, 2017

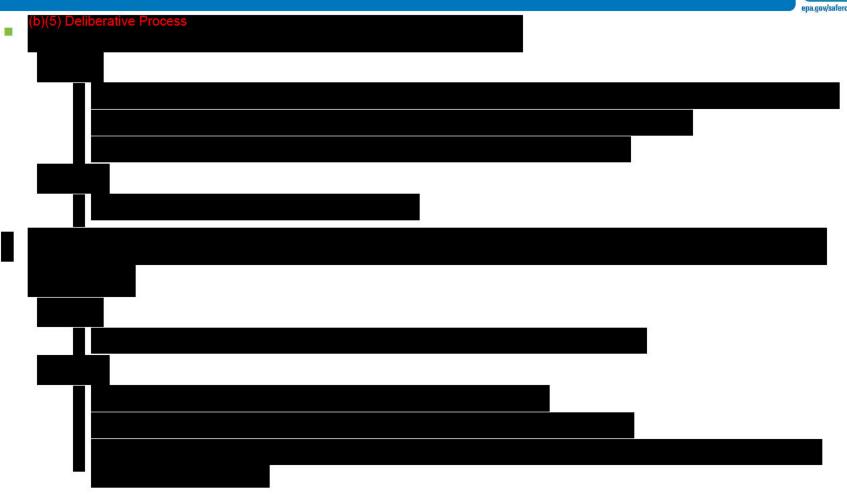
## Cot'n Wash Now Pushing Back on Sunset—Arguments:



- Special status as existing partner, seeking only to renew partnership
- Reliance on partnership to differentiate their products in the marketplace
- Infringement of equal protection and due process rights

## **Options for Consideration**





## Thank you!



## Discussion of Liquid Packets

### Dicamba: Meeting with State Extension Representatives July 28, 2017

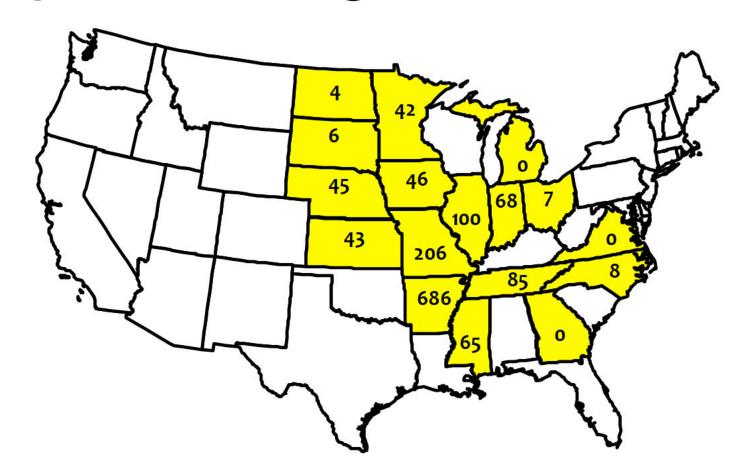
### Agenda

- I. Meeting Introductions OPP & USDA
- II. Meeting Format (RD) Kenny/Baris
- III. Mapping of incidents/damage overview (Bradley)
- **IV. Extension's Input on Dicamba Incidents (30-40 min)** *EPA is soliciting feedback from extension agents focusing on information that could help remedy the unacceptable dicamba incidents in the field. We would like to hear from each of the extension experts with their insights related especially to the following:* 
  - 1. Based on information available to you, so far, what would you describe as the leading causes of crop damage incidents in your state?
  - 2. What are you seeing out in the field that led you to that conclusion? Are you working on any additional data that is relevant to the issues? Are you able to share any of this information with the EPA?
  - 3. Based on the leading causes, what approaches would you recommend to fix the problem?

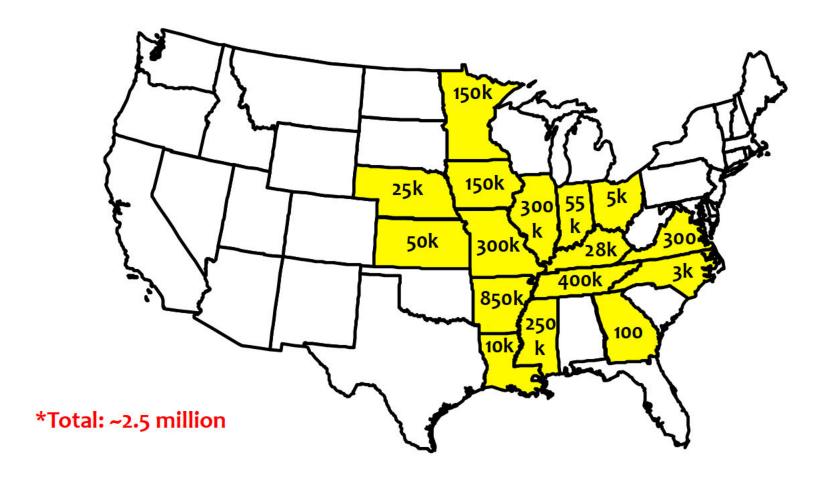
Arkansas (Norsworthy, Barber, and Scott)
Georgia (Culpepper and Prostko)
Illinois (Hager)
Indiana (Johnson and Young)
Iowa (Hartzler and Owen)
Kansas (Peterson)
Kentucky (Barrett)
Mississippi (Bond)
Missouri (Bradley)
Ohio (Loux)
Tennessee (Steckel and Mueller)

- V. Volatility Data/Discussion (Bradley) (20-30 min)
- VI. Additional Discussion and Questions (time permitting)
- VII. Closing Remarks/next steps

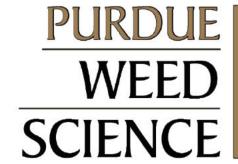
# Official Dicamba-related Injury Investigations as Reported by State Departments of Agriculture (\*as of July 19, 2017)



# Estimates of Dicamba-injured Soybean Acreage in the U.S. as Reported by State Extension Weed Scientists (\*as of July 19, 2017)





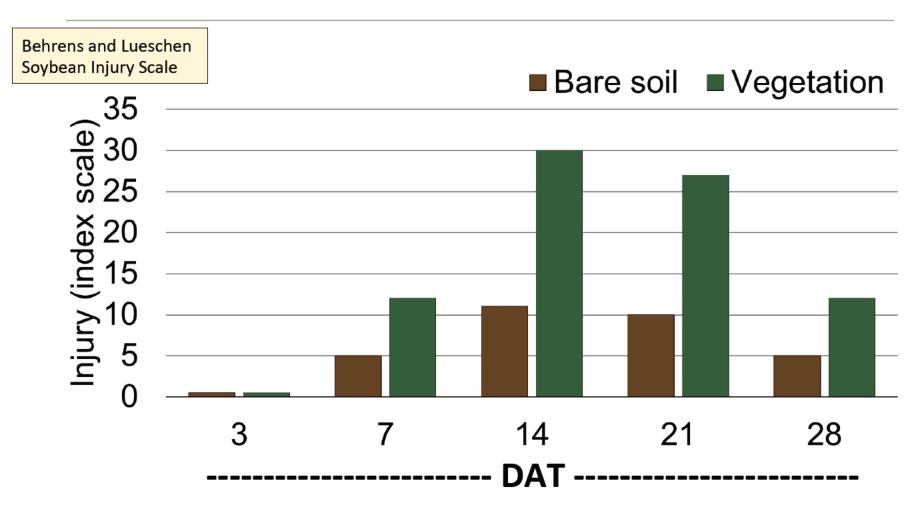


# Influence of Application Factors on Dicamba Volatility

Jamie L Long
Department of Botany and Plant Pathology
Purdue University, West Lafayette, IN

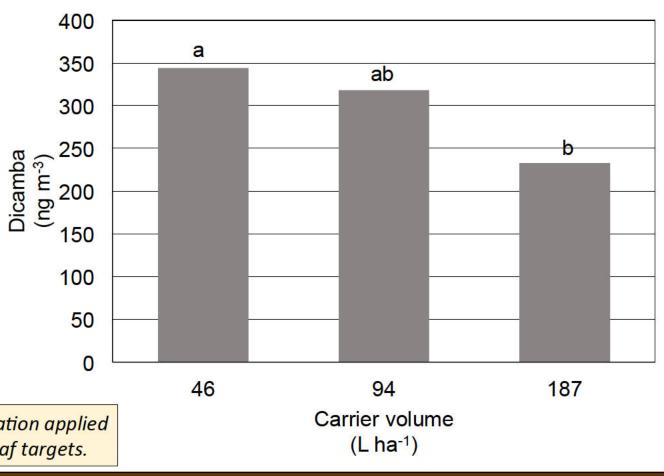
## Dicamba Volatility by Target Surface

Field Low Tunnel Experiments (3 site-years)



## Carrier Volume

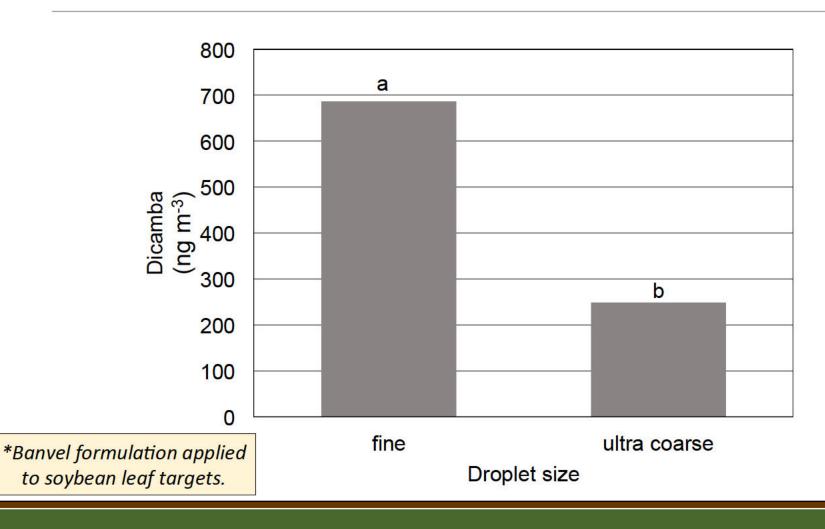
## Vapor Chamber Experiment



\*Banvel formulation applied to soybean leaf targets.

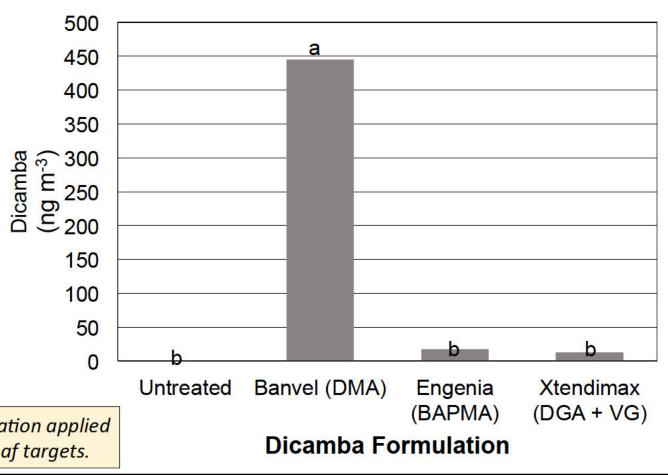
## **Droplet Size**

## Vapor Chamber Experiment



## Herbicide Formulation

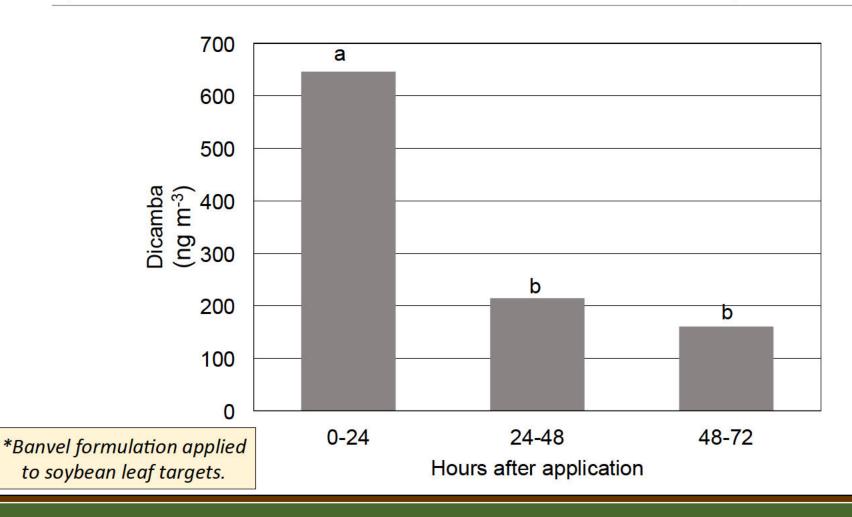
## Vapor Chamber Experiment



\*Banvel formulation applied to soybean leaf targets.

## Dicamba Volatility from Soybean Foliage

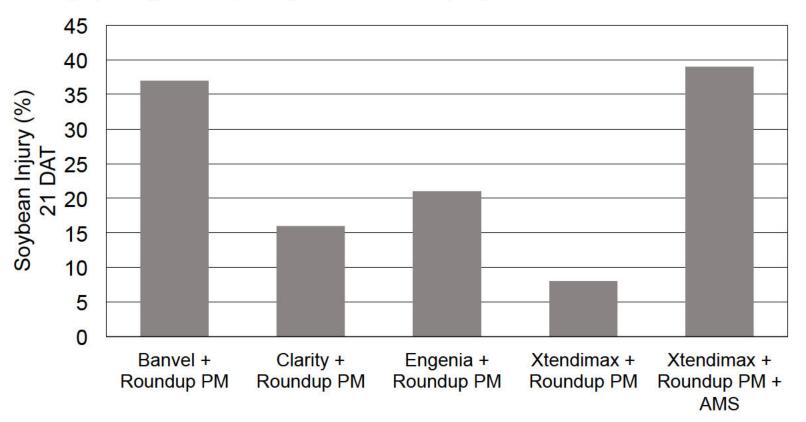
Vapor Chamber Experiment (Pooled over sensitive/tolerant varieties)



## PRELIMINARY 2017 DATA Dicamba Volatility by Herbicide

Field Low Tunnel Experiment

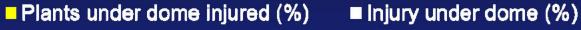
<u>Methods:</u> Sprayed 3 flats with bare soil for each treatment and placed in the center of 2 soybean rows. Injury rating is for soybean plants immediately adjacent to the flats.

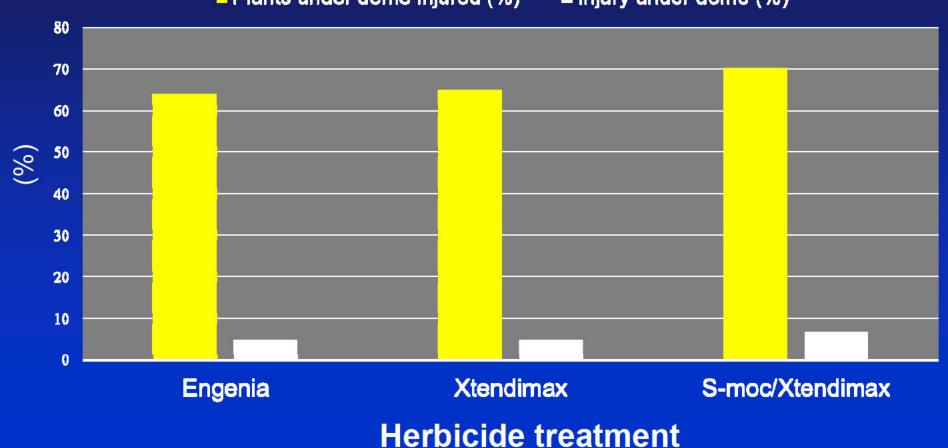




# Tunnel Volatility Study (Soybean)

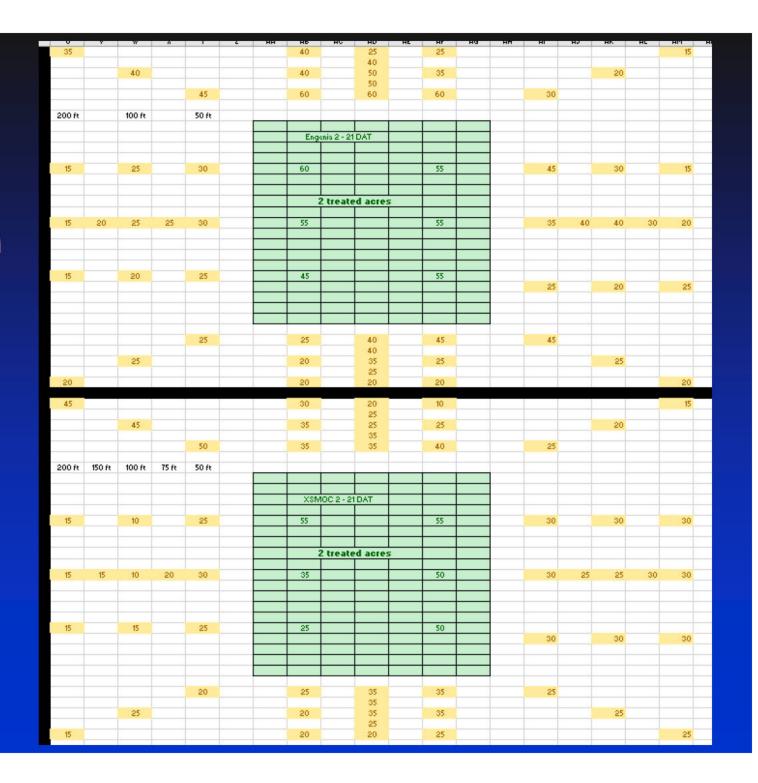
13 days after treatment





8:00 – 8:15 PM June 13, 2017

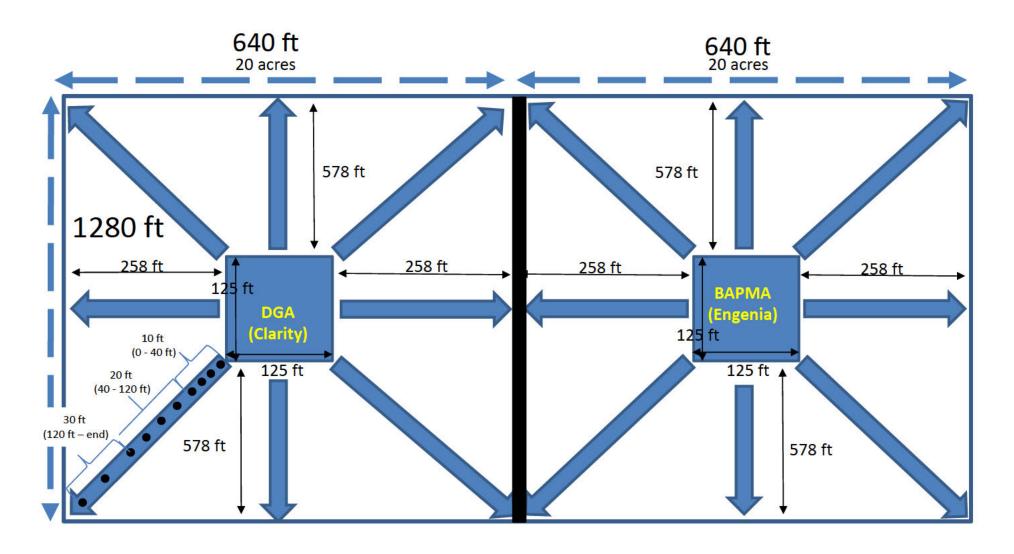
Avg: 3.6 mph 1 to 6 mph



### Soybean placed in treated field 30 minutes after Engenia application



## Physical Drift, Vapor Drift, and Overall Drift Comparison





### Comparison of two dicamba formulations for risk of off-target movement to soybean

G.T. Jones<sup>1</sup>, J.K. Norsworthy<sup>1</sup>, L.T. Barber<sup>2</sup>, J.K Green<sup>1</sup>, C.J. Meyer<sup>1</sup>, and N.R. Steppig<sup>1</sup> Department of Crop, Soil, and Environmental Sciences, University of Arkansas, Fayetteville, AR <sup>2</sup>University of Arkansas Research and Extension Service, Lonoke, AR



#### Introduction

- · With the advent of dicamba-resistant crops, there will be greater possibility for off-target movement of dicamba due to
- Soybean response to Clarity (DGA dicamba) and Banvel (DMA dicamba) has been documented to be similar (Egan and Mortensen 2012); It has yet to be determined if soybean response to Engenia (BÁPMA dicamba) will be similar.
- Previous research has documented Clarity (diglycolamine dicamba) to have reduced secondary (volatile) loss of 94% when compared to Banvel (dimethylamine dicamba) (Egan and
- Other research has documented a 50% decrease in detection. by air samplers when Clarity was applied over Banvel (Mueller
- Engenia (N,N-Bis-[aminopropyl] methylamine dicamba) is claimed to have decreased secondary loss in regard to Clarity; however, no peer reviewed research is available concerning

### Hypotheses

· Soybean response from Clarity and Engenia will be similar. · Engenia will display reduced secondary injury to soybean in regard to Clarity

### Objective

 To separate the combined effects of primary and secondary drift to sovbean

### **Materials and Methods**

- · Trials were established in 2015 and 2016 at the Northeast Research & Extension Center in Keiser AR
- In two side-by-side 8 ha fields, Engenia and Clarity were simultaneously applied to a 1,444 m<sup>2</sup> area at 560 g ae ha<sup>-1</sup> using Bowman Mudmasters (Bowman Manufacturing, Newport, AR) (Figure 1).
- The Mudmasters were equipped with identical 7.6 m spray booms and were calibrated to deliver 94 L hard from TTI 11003 nozzles (TeeJet Technologies, Springfield, IL) while traveling
- Plots were established in each cardinal direction.
- · Every 3 m for the first 12 m
- Every 6 m up to 36 m
- Every 9 m up to 72 m
- · Every 12 m until the edge of the field was reached
- Three sets of 4-5 plants were marked at each distance and 19 L buckets were used to shield plants from primary (physical) and secondary drift
  - . The first set was only exposed to secondary drift (bucket was placed over these plants during application).
  - · The second set was only exposed to primary drift (bucket was placed over these plants 30 min after application where it remained for 24 hours).
  - The last set was never covered
- An additional rate titration experiment was established using ten rates ranging from .0056 to 56 g ae ha-1 of each herbicide on the same day as the large drift trials.

### Data Collection and Analysis

- · Visual injury ratings were collected at 7, 14, and 21 days after application (DAA) from the drift trials and rate titration
- · Tissue samples were taken at 7 DAA from the Clarity rate titration and large drift trial to examine tissue concentration of
- Analysis of covariance (ANCOVA) was performed using SAS (SAS Institute, Cary, NC) to examine differences in response of sovbean to Clarity and Engenia.
- Injury ratings in the drift experiment were paired with corresponding injury in the rate titration experiment to estimate the dose received at distances downwind.

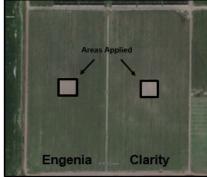


Figure 1. Aerial view of the large drift experiment approximate

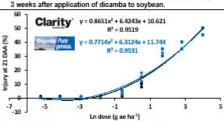


Figure 2. 2015 dose response curves for Clarity and Engenia.

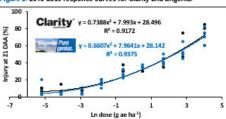


Figure 3. 2016 dose response curves for Clarity and Engenia.

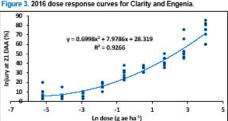


Figure 4. 2016 combined dose response curve for Clarity and Engenia.

Table 1. Secondary injury at 21 DAAs and approximate doses at distances along the north transect in the 2016 drift experiment.

Distance (m)	Clarity		Engenia	
	Injury	Doseb	Injury	Doseb
3	40	3.3865	50	9.3353
6	45	5.7939	50	9.3353
9	40	3.3865	40	3.3865
12	40	3.3865	40	3.3865
18	35	1.8641	32	1.2659
24	30	0.9664	30	0.9664
30	15	0.0939	15	0.0939
36	15	0.0939	10	0.0383
45	15	0.0939	8	0.0263
54	10	0.0383	5	0.0147
63	5	0.0147	0	0
72	7	0.0217	0	0
85	5	0.0147	0	0
97	5	0.0147	0	0
109	5	0.0147	0	0
121	5	0.0147	0	0
133	0	0.0099	0	0
145	0	0.0099	0	0
157	0	0.0099	0	0
169	0	0.0099	0	0

<sup>a</sup> Days after application

b g ae ha-1

#### Results

- ANCOVA results from the rate titration experiment docum no difference in soybean sensitivity between Clarity and Engenia either year (Figures 2 and 3) (Fail to reject hypot A); therefore, data were combined to form a single dose response curve to allow for dose estimation in the Clarity and Engenia large drift experiments (Figure 4 and Table 1)
- An unexpected rainfall event of 2 cm occurred 6 hours after application in 2015 which ceased possible volatilization hrens and Lueschen 1979).
- · In 2016, the downwind distance to 5% injury via secondary drift from Engenia was decreased by 57 m when compared to Clarity at 21 DAA (Fail to reject hypothesis B).

### Conclusions

- The higher degree of soybean injury observed in 2016 was likely due to a lack of rainfall or irrigation for several days prior to and after application (Andersen et al. 2004) (Figures 3 and 4)
- Unexpected rain events disrupted the study in 2015; however, 2016 results documented the distance to secondary injury to decrease by 47% when Engenia was applied when compared
- · This research suggests that Engenia is less prone to secondary drift than DGA forms of dicamba such as Clarity.

#### Literature Cited

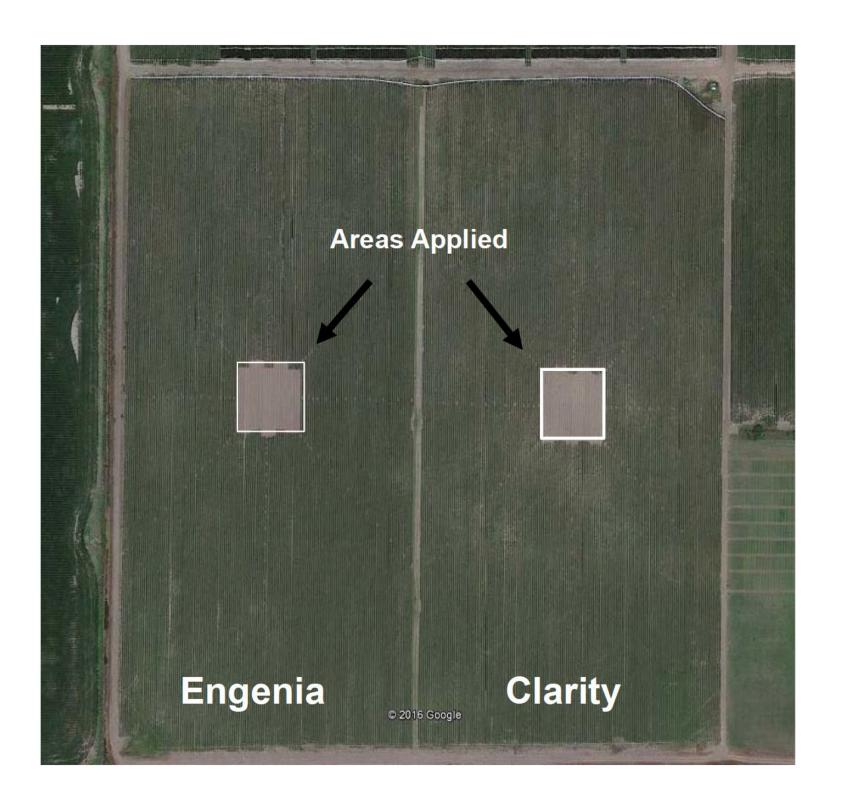
- Andersen SM, Clay SA, Wrage LJ, Matthees D (2004) Soybean foliage residues of dicamba and 2,4-D and correlation to
- application rates and yield. Agron J 96:750-760
  Behrens R, Lueschen WE (1979) Dicamba volatility. Weed Sci
- Egan JF, Mortensen (2012) Quantifying vapor drift of dicamba herbicides applied to soybean. Environmental Toxicology and Chemistry 31:1023-1031
- Mueller TC, Wright DR, Re mund KM (2013) Effect of formulation and application time of day on detecting dicamba in the air under field conditions. Weed Sci 61:586-593

### Acknowledgements









## Effect of adding Roundup PowerMax to Engenia on vapor losses under field conditions

Thomas C Mueller
University of Tennessee
July, 2017

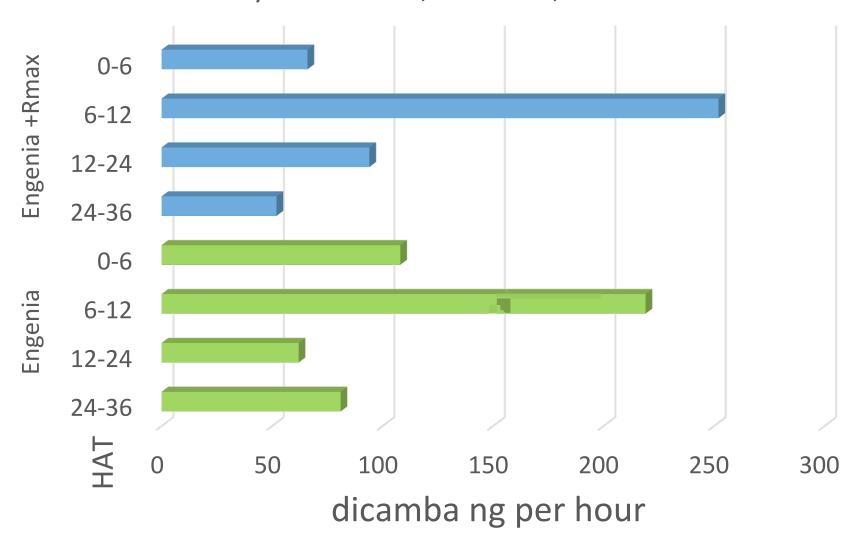




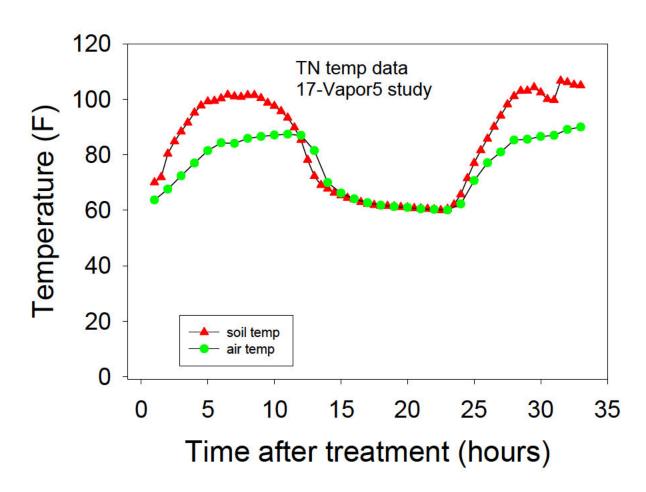
## Background

- Dicamba injury to soybeans widespread throughout soybean producing regions of Tennessee
- This study requested by Tennessee Soybean Promotion Board (TSPB)
- Specific question :
- What is the effect (if any) on dicamba volatility from adding RoundupPowermax (Rmax) to the tank while applying Engenia

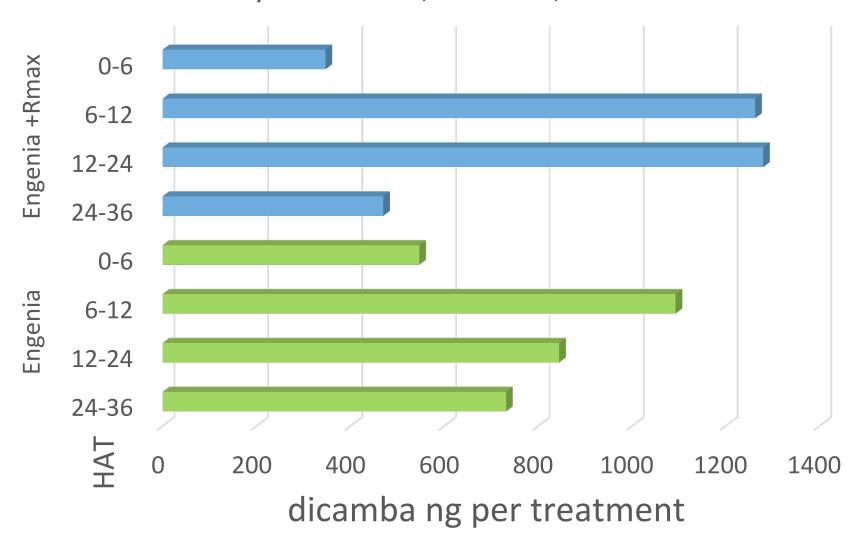
Field Volatility of Dicamba, Knoxville, TN June 2017



## temperature



Field Volatility of Dicamba, Knoxville, TN June 2017



## Observations

- All samples had detected concentrations of dicamba
- No apparent effect of adding Rmax on dicamba volatility from Engenia
- Greatest dicamba concentrations at 6-12 and 12-24 HAT sampling intervals
- Most dicamba loss to atmosphere per hour was in the first afternoon after spraying (6-12 HAT)

## Our Efforts to Understand the Role of Formulations & Temperature Inversions in the Off-site Movement of Dicamba

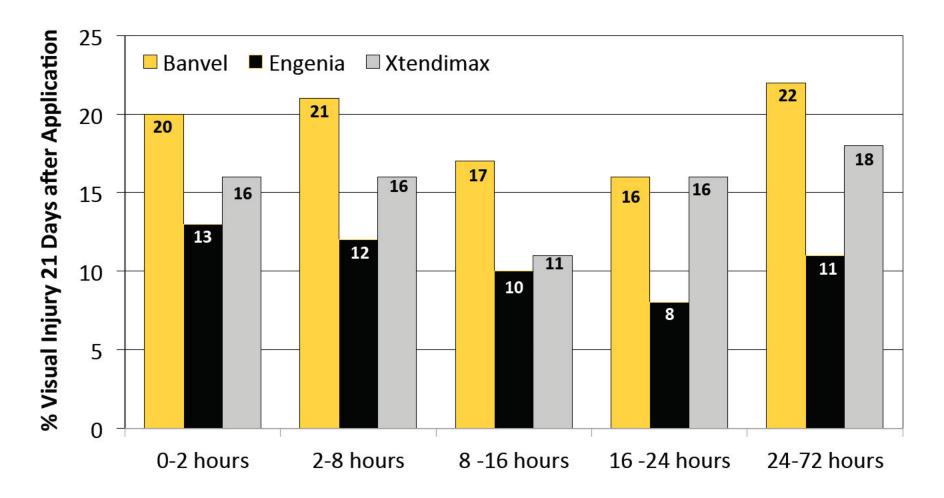
### Methods:

- Banvel, Engenia, and Xtendimax sprayed in geographically separate areas.
- Air samples taken and indicator plants placed at regular intervals after treatment



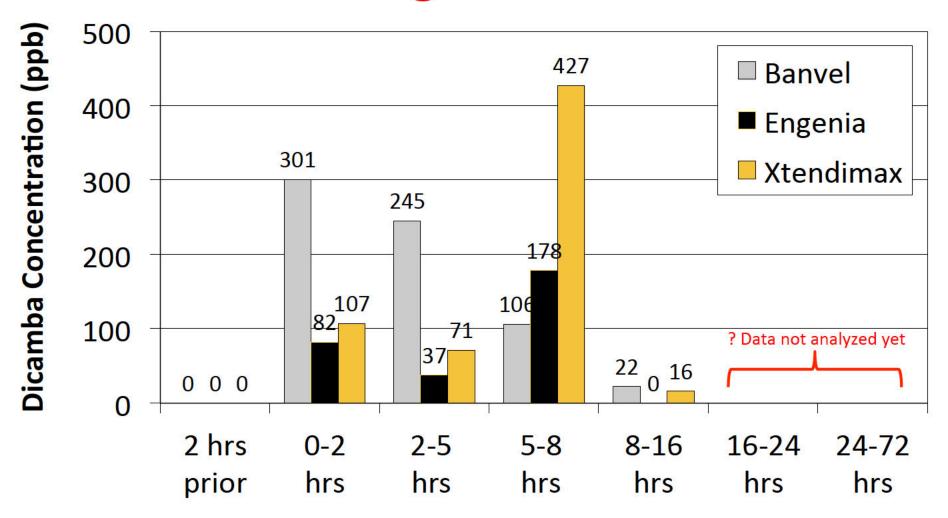


## Evaluation of Soybean "Indicator Plant" Injury Following Application of 3 Dicamba Formulations



**Time After Treatment** 

# Some Preliminary Air Sampling Results with Engenia and XtendiMax



Time in Comparison to Treatment

### Briefing on Lead: August 4, 2017 Overview of Task Force, EJ2020 and Lead in Indian Country

Amanda Hauff, OCSPP's Tribal and Environmental Justice Program Manager

### President's Task Force on Environmental Health Risks and Safety to Children Background Information

- The President's Task Force is the focal point for coordinating the federal government's efforts to
  explore, understand, and improve children's environmental health. The Task Force was
  established by Executive Order 13045 in 1997 calling for each federal agency to "ensure that
  its policies, programs, activities, and standards address disproportionate risks to children that
  result from environmental health risks and safety risk."
- Objectives of the President's Task Force are to:
  - o Identify priority issues of environmental health and safety risks to children that can best addressed by federal interagency efforts
  - Recommend and implement interagency actions to protect and promote children's environmental health and safety
  - Communicate with federal, state, and local decision makers to protect children from environmental and safety risk
- Members
  - 11 Federal Agencies
  - 6 White House Offices
  - Co-chairs: EPA Administrator, HHS Secretary
- Structure
  - Senior Staff Steering Committee; Co-Chairs: EPA, HHS
  - Subcommittees: lead exposures, chemical exposures, asthma disparities, and healthy settings

#### OCSPP's Role

- Serves on the Senior Staff Steering Committee to support the work of the Task Force
- Serves on the Lead and Chemical Exposures Sub-Committees

#### OCSPP Activities and Accomplishments

- Published the Key Federal Programs to Reduce Childhood Lead Exposures and Eliminate
   Associated Health Impacts report which identifies efforts of nine federal agencies activities to
   understand, prevent and reduce various source of lead exposures among children
- Developed, and coordinated a new comprehensive federal strategy outline to reduce childhood lead exposures and eliminate associated health impacts; Fostered federal agencies efforts to compliment EPA's intra-agency efforts to focus on minority, low-income, vulnerable populations
- Crafted research and development questions to advance scientific understanding of the effects, evaluation, and control of lead hazards in children's environments; these questions will serve as the starting point for federal agencies to conduct collaborative research in order to take meaningful action

- Fostered and facilitated new discussions and activities to examine, understand, and include childhood lead exposure and disparities in Indian country
- Developed community engagement and dissemination plans for the Strategy

#### **Projected Timeline**

• TBD: First draft of the Federal Lead Strategy

#### Environmental Justice Strategic Plan (EJ2020)

#### **Background Information**

- EPA's Environmental Justice Strategic Plan focused the Agency on environmental and public health issues and challenges confronting the nation's minority, low-income, tribal and indigenous populations
- EJ2020 consists of eight priority areas and four significant national environmental justice challenges
- Lead Disparities were identified a Significant National Environmental Justice Challenge
  - Goal: Eliminate disparities in childhood blood lead levels as an integral part of reducing lead exposures for all people
  - EPA will take action to address childhood lead exposures and health disparities in a holistic manner in order to focus Agency resources, technical assistance, and comprehensive solutions to reduce sources of lead contamination in overburdened communities

#### OCSPP's Role

• Serves as the Agency's principal on *Lead Disparities* actions, located on pages 37-41.

#### Lead Disparities Overview

The *Lead Disparities* section provides:

- An aspirational goal to eliminate disparities in childhood blood lead levels, while reducing lead exposures for all people;
- A program measure that identifies a comparison of blood lead levels in low-income children compared to non-low-income children;
- Background information on the toxicity of lead and exposures; as well as
- EPA's three main objectives on lead:
  - I. Identify concentrated geographic areas with the most overburdened communities where lead exposures are highest;
  - II. Create collaborative strategies and approaches to take action to reduce sources of lead contamination; and
  - III. Take national actions to reduce lead in drinking water.

Most importantly, EPA will seek to collaborate with partners to address the above objectives by leveraging existing projects and activities as well as identifying new opportunities to take collaborative action(s).

#### Lead Disparities Objectives

EPA will take action to address childhood lead exposures and health disparities in a holistic manner in order to focus Agency resources, technical assistance and comprehensive solutions to reduce sources of lead contamination in overburdened communities.

To eliminate disparities in childhood blood lead levels, EPA will convene partners including other federal agencies, state, tribes, local government, non-profit organizations and community stakeholders, to accomplish the following:

#### I. Identify concentrated geographic areas with the most overburdened communities

In collaboration with partners, EPA will take the following steps to address disparities in blood lead levels in children by focusing on communities where these disparities are most pronounced. EPA will define a subset of the most overburdened communities where lead exposures are highest, based on factors such as:

- Household income;
- Age of housing in the community;
- Proximity to a Superfund site containing lead;
- Proximity to other sources of lead contamination such as industrial sites and highways;
- Drinking water supplied by utilities that exceed the Lead and Copper Rule action level for lead;
- Non-attainment of the lead National Ambient Air Quality Standards (NAAQS); and
- Additional evidence of factors that contribute to elevated blood lead levels among children.

The identification of targeted areas with the highest risk of lead exposure to children will better allow EPA and its partners to focus specific resources aimed at ultimately eliminating harmful exposures. This, in turn, will aid in the elimination of disparities in lead exposure currently seen in the United States.

#### II. Reduce sources of lead contamination

To reduce sources of lead contamination, EPA will develop strategies and unique approaches with all levels of government, the private sector, non-government organizations and community partners to:

- Educate communities on sources of lead contamination and the health effects of lead; Raise awareness of lead-based paint exposure and prevention tactics;
- Increase efforts to ensure adequate lead-based paint workforces (e.g., inspectors, contractors, trainers, etc.);
- Increase technical assistance to states and public water systems to optimize corrosion control treatment and remove lead service lines, if lead in drinking water is a source contributor;
- Raise awareness of actions residents and the community can take to reduce lead in drinking water;
- Develop community-based sampling programs to test soil, paint and drinking water for elevated lead levels;
- Identify best practices and transfer lessons learned;
- Facilitate data-sharing between health and environmental agencies;
- Improve the use of data from screening programs; and
- Increase financial assistance to address lead hazards at the community level, to the extent resources are available.

#### **III.** National actions to reduce lead in drinking water (Note: OW is the principal for this effort)

EPA plans to take actions to reduce lead in drinking water by strengthening protections provided by the Lead and Copper Rule. EPA will:

- Work closely with states and public water systems to enhance oversight and provide guidance on tap water sampling;
- Improve guidance and implementation for corrosion control and lead mitigation; and
- Identify best practices that can be applied to communities.

In addition, EPA plans to consider long-term revisions to the Lead and Copper Rule to improve public health protection by making substantive changes to streamline the rule requirements. EPA's primary goals in considering Lead and Copper Rule long-term revisions are to:

- Improve the effectiveness of the corrosion control treatment in reducing exposure to lead and copper, and
- Trigger additional actions that equitably reduce the public's exposures to lead and copper when corrosion control treatment alone is not effective.

#### OCSPP Activities and Accomplishments

- Cultivated, coordinated and published Lead Disparities chapter
- Conducted community engagement; Revised strategy based off of constituent's feedback
- Established intra-agency team and sub-committee(s)
- Developed and refined Lead Inventory Structure to create an interactive platform for information sharing and Agency use
- Drafting the methodology to accomplish Objective I
  - Identified potential products: 1) Interactive map for analyses; 2) National Lead Analysis Report (supplemental analyses of information and findings); 3) White Paper on data gaps and needs
  - Analyzing existing authoritative mapping layers and geo-coded data sets
  - Identify/obtain CDC data on national BLL; identify gaps; develop/take actions to populate information for gaps

#### Lead Inventory Structure Outline

EPA's Lead Disparities Team will develop a Lead Dashboard that provides an inventory of Agency resources, activities and information to be used as a platform for information sharing to analyze EPA's lead work and to be used to take actions towards eliminating disparities in childhood lead levels for vulnerable populations. In addition, this will serve as a platform to ensure Agency coordination, collaboration and communications.

Information will be structured into the below major categories:

#### I. Partnerships, Projects, and Grants

- a. Partnership an arrangement where parties may be individuals, business, interest-based organizations, schools, government, or combinations
- b. Project planned set of interrelated tasks to be executed over a fixed period and within certain cost and other limitations
- c. Grant funding that does not have to be repaid

#### II. Outreach, Education, Training Materials and Events

- a. Outreach, Education, Training Materials products designed to explain information and encourage people to take action
- b. Events a planned public occasion

#### III. EPA Data Visualization and Analytical Tools, Applications, and Statistical Models

- a. Data Visualization Tool a tool used to present data in a pictorial, graphical, visual context to enable decision-makers to see analytics presented visually
- b. Data Analytical Tool a tool used to display and analyze multiple sets of variation data on a single graph; usually provides high quality data for discrete chemicals; software that performs one or more functions and that's been specifically built for a specific solution data collection and analysis tools box and whisker plot, control chart, histogram, scatter diagram, survey
- c. Application an application, especially as downloaded by a user to a mobile device
- d. Statistical Model a mathematical model, which embodies a set of assumptions concerning the generation of some sample data, and similar data from a larger population; a statistical model often in considerably idealized form, the data-generating process

#### IV. Data Collection, Analysis, Evaluation, and Use

- a. Data collection the process of gathering and measuring information on targeted variables in an established systematic function, which then enables one to answer relevant questions and evaluate outcome
- Data Analysis the process of inspecting, cleansing, transforming, and modeling data with the goal of discovering useful information, suggesting conclusions and supporting decision-making
- c. Data Evaluation the process of evaluating data using analytical and logical reasoning to examine each component of the data provided; data from various sources is gathered, reviewed, and then analyzed to form some sort of finding or conclusion
- d. Data Use facts that can be used in calculating, reasoning, or planning

### V. EPA Data Analysis and Evaluation of National Health and Nutrition Examination Survey (NHANES) Data

- a. NHANES Data Analysis the process of inspecting, cleansing, transforming, and modeling data with the goal of discovering useful information, suggesting conclusions and supporting decision-making
- b. NHANES Data Evaluation the process of evaluating data using analytical and logical reasoning to examine each component of the data provided; data from various sources is gathered, reviewed, and then analyzed to form some sort of finding or conclusion
- c. NHANES Data Use facts that can be used in calculating, reasoning, or planning

#### Projected Timeline

• (b)(5) Deliberative Process

- October: Obtain national BLL exposure information and identify data gaps
- January: Execute methodology plans

#### **Lead in Indian Country**

#### **Background Information**

- Identified the need to take efforts to better understand, assess, and include childhood lead exposure and disparities in Indian country into Agency and Task Force efforts
  - For example, we need to:
    - Understand and identify BLL data, exposures, and unique cultural exposures
    - Identify success stories, best practices, needs, impacts, etc.
    - Coordinate and collaborate further as an Agency and the Federal Government
    - Coordinate and collaborate with tribes, tribal communities and tribal organizations

#### OCSPP's Role

Serves as Agency and Task Force principal

#### Objectives

- Assess current status of lead exposures in Indian country for the Agency and Task Force
  - Identify, understand, and explore information to address tribal lead disparities and exposures
    - Quantify and qualify tribal disparities
- Build tribal-federal partnerships, networking and participation
- Enhance/leverage resources, technical assistance, and information sharing to improve outreach, education and actions in Indian country
- Allow for Tribal Partnerships Groups to take a principal role to improve and disseminate preventative communications, etc.

#### OCSPP Activities and Accomplishments

- Established networks to serve as resources, advocates, and collaborators; Facilitated organizational changes to include approaches to address childhood lead disparities and exposures in Indian country
- Facilitated inter and intra agency discussions on issues, needs and gaps
- Analyzing EPA work in Indian country to provide a sense of issues and leverage existing materials, resources, best practices, etc.

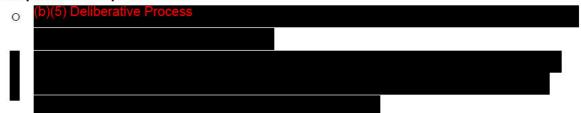
#### Projected Timeline

- Ongoing: Convene partners (e.g., NTTC, TSC, ORD, OCHP, OEJ, HUD, HHS, etc.) to discuss lead in Indian country and activities
  - o Components include: data, outreach/education, planning, collaborations, etc.
- October: Finish EPA's Snapshot of work in Indian country which provides existing materials, information, success stories, challenges and feedback from EPA's Tribal Program
- November: Develop first draft of strategic plan

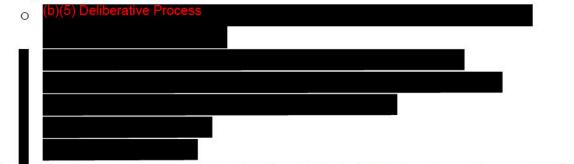
#### **PFAS Work Group Activity Summary**

#### <u>Cross-Agency PFAS Human Health Toxicity Workgroup – August 30, 2017</u>

- Goal: Address public concerns and inform risk mitigation activities by filling data gaps related to human health toxicity
- Anticipated accomplishments:



Anticipated upcoming milestones:



Agency leads: Workgroup co-chairs - Kathleen Raffaele (OLEM) and Lynn Flowers (ORD)

#### PFAS Priorities: Cross-Agency Data Quality Workgroup - July 13, 2017

- Goal: Identify data quality issues and guidelines to establish laboratory data submission and national data validation procedures related to PFAS and LC/MS/MS.
- Anticipated accomplishments:



Anticipated upcoming milestones:



Agency leads: Workgroup co-chairs - Barry Pepich (Region 10), Cynthia Caporale (Region 3),

#### PFAS Priorities: Cross-Agency Methods Workgroup July 13, 2017

- Goal: Establish validated methods for measuring the amount of PFAS in different environmental media and for biomonitoring.
- Anticipated accomplishments:



Anticipated upcoming milestones:



**Agency leads**: Workgroup co-chairs – Cynthia Caporale (Region 3), Christopher Impelliteri (ORD), and Schatzi Fitz-James (OLEM)

 Note: This priority activity is one of the three existing PFAS working groups and closely coordinates with the data quality workgroup.

### OPP Human Health Risk Assessment Overview

Briefing For Nancy Beck September 14, 2017

### SEPA Roadmap

- Basis
- Risk Assessment
  - Hazard
  - Exposure
  - Characterization
- Topical Issues

# **SEPA** Legislative Basis

### FIFRA (Risk/Benefit Standard)

- Occupational Risk Assessment
- Ecological Risk Assessment

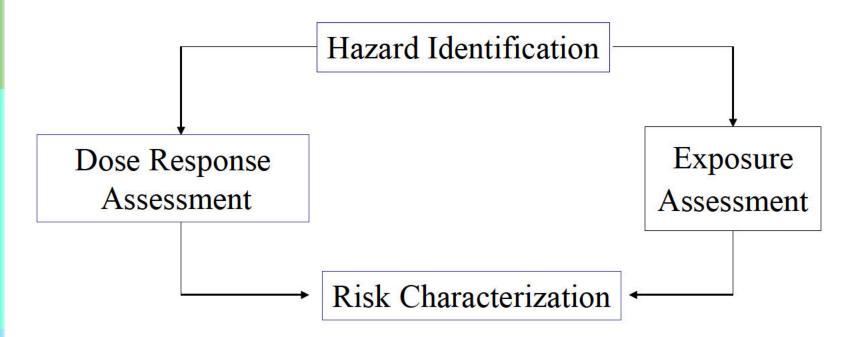
### FFDCA/FQPA (Risk-Only Standard)

- Human Health Risk Assessment
  - Dietary Exposure
  - Residential Exposure

#### **Food Quality Protection Act**

"...reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information."

### **SEPA** Basic Construct



<sup>\*</sup>From the National Research Council's *Risk Assessment in the Federal Government: Managing the Process*, 1983. http://books.nap.edu/books/030904894X/html/1.html



### How Risk Is Expressed

Dietary Risks: % of acute(aPAD) & chronic (cPAD)

PAD = <u>Point of Departure (e.g., NOAEL)</u> Uncertainty Factors (includes FQPA)

%PAD = Exposure x 100PAD

Occupational/Residential Risks: MOE or Margin of Exposure

MOE = Point of Departure (e.g., NOAEL)
Exposure

Target MOE = Uncertainty Factors (Residential Includes FQPA)

Cancer risks are expressed as population based estimate

Typically a range of results presented, based on 1986 Barolo Memo guidance

# Scientific Rigor

- Well established guidelines and GLP criteria are basis of methods
- Key approaches and data sources have undergone extensive external scientific peer review
- Risk assessments are vetted in public participation process
- Many methods are broadly accepted on an international level
- Leaders in cutting edge science policy development



# Key Definitions

- Endpoint: The adverse effect upon which the risk assessment is based
- Control: Background response with dosing (dose = zero)
- Lowest Observed Adverse Effect Level (LOAEL): Lowest dose from a study at which adverse effects are observed
- No Observed Adverse Effects Level (NOAEL): The dose at which no adverse effects are observed
- Point of Departure (POD): The dose level used to quantify risk (generic)
- Population Adjusted Dose (PAD): Dose level used to quantify risks in dietary assessments, represents the POD adjusted with all appropriate safety factors including FQPA
  - APAD = Acute PAD, CPAD = Chronic PAD
  - PAD = RfD with FQPA factor also applied

### **SEPA** Hazard Identification

- Battery of toxicology studies are required
   https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-870-health-effects-test-guidelines
- Data intended to identify variety of potential adverse effects
  - e.g., neurotoxicity, reproduction and developmental toxicity, cancer, immunotoxicity
- Studies are conducted in a variety of species e.g., mice, rats, rabbits, dogs
- Treatments range from single (acute) exposure to repeated longer term exposures (up to 2 yrs)
- Non-guideline data important too
  - e.g., comparative cholinesterase (CCA) and comparative thyroid (CTA)
- Fit for Purpose approaches being used as appropriate
  - e.g., HASPOC/data waiver process



### Hazard Identification

- Process of identifying the potential health effects as a result of various types of chemical exposure
- Output is "Points of Departure" or POD
- Goal is to match route & duration of exposure

Typical Scenarios & Durations	Oral	Dermal	Inhalation
Acute (1 Day)	<b>√</b> Dietary		
Short-Term (up to 1 Month)	✓ Incidental	✓	✓
Intermediate-Term (up to 6 Months)	✓ Incidental	✓	✓
Chronic (> 6 Months)	<b>√</b> Dietary		

**FQPA** Safety

Factor

### **SEPA** Uncertainty/Safety Factors

- Intraspecies variability among humans
- Interspecies extrapolating animal data to humans
  - **Extrapolating from less-than-lifetime to lifetime** exposures
- LOAEL to NOAEL
- Incomplete data base
- **Increased concern for susceptibility of infants** and children not addressed by other safety factors

Population Adjusted Dose (PAD) RfD Incomplete Unique Intraspecies Interspecies LOAEL to Subchronic Modifyina to Complete **FQPA** Factor NOAEL to Chronic Factor Factor Database Concerns Traditional UFs ...... FQPA SFs Areas of overlap with Traditional UFs which deal with data problems

Generally 10X unless a smaller factor can be shown to be protective

Maximum = 3000

Example of factor application to develop PAD for dietary risk assessment



# Exposure Types

Dietary Exposure



Residential Exposure (General Public)



Occupational Exposure





# Key Factors In Exposure Assessment



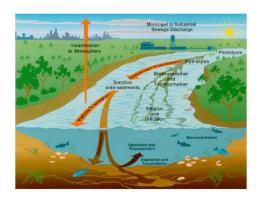
Use Information (rate, type, & crop)



Chemistry



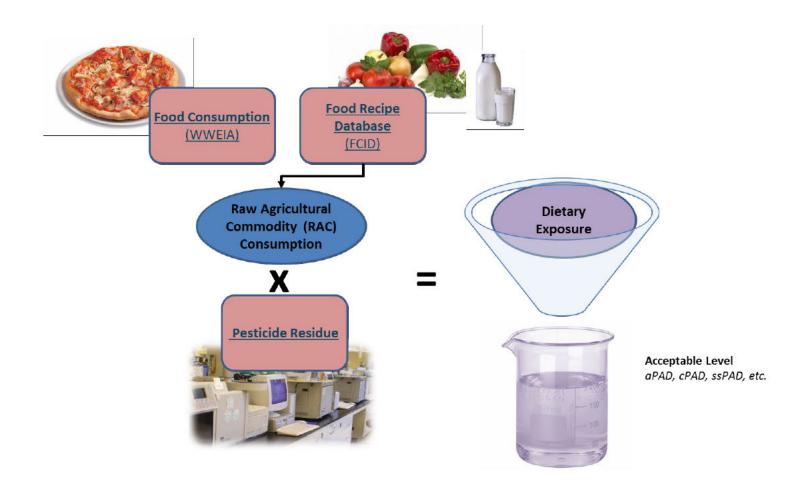
**Human Behaviors** 



Fate & Transport

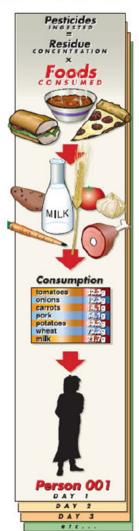
### **\$EPA**

# Dietary Exposure





# Dietary Exposure



Consumption X Residue = Dietary Exposure

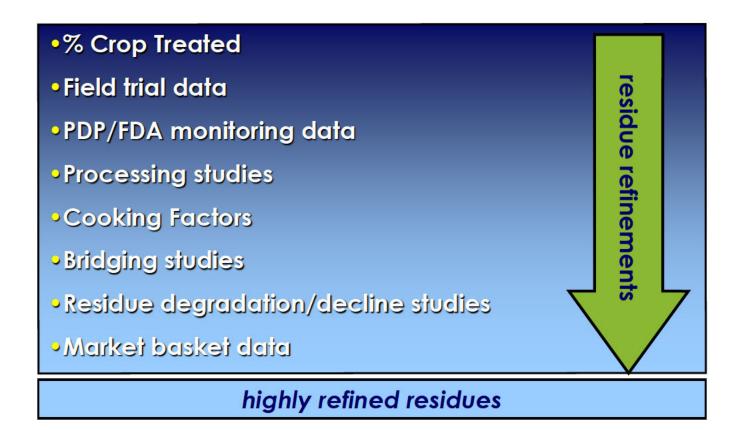
- Assessments range from simple to complex, but based on same general exposure algorithm.
- OPP uses a data-driven approach
  - USDA's What We Eat In America (WWEIA) Survey
     Nationally representative food consumption survey
  - U.S. EPA's Food Commodity Intake Database (FCID)

Recipe database that links WWEIA foods to residue data

Residue Data
 Sources vary depending on level of refinement

# **SEPA** Refinement Approach

### No refinements: Tolerance-level residues and 100%CT



### **\$EPA**

### Tolerances & MRLs

- Amount that can legally remain in or on foods
- Label-compliance tool, not a health-based standard
- Tolerances set on food and/or feed crops
- Based on results from field trials designed to identify the highest concentrations expected
  - Use maximum application rates
  - Maximum number of applications
  - Shortest application to harvest interval
- Generally, actual measured residues in food are lower than tolerances
  - e.g., degradation during distribution and storage, washing

### **\$EPA**

### Residential Exposure

- Exposure from uses
  - In and around homes
  - Athletic fields and golf courses
  - Public areas
- Exposure scenario based pathways
  - Handlers
  - Post-application
    - Index lifestages considered
- Routes of exposure
  - Dermal (application and post-application)
  - Inhalation (application and post-application)
  - Oral (post-application; children only)
- Key tool SOPs For Residential Exposure Assessment



### **SEPA** Residential Handlers

$$\frac{lb\ Chem X}{Area} \times \frac{Area}{day} \times \frac{mg\ Chem X\ Exposure}{lb\ Chem X\ Handled} \div kg\ BW = \text{Exposure}\ (mg/kg/d)$$

MOE = Point of Departure (e.g., NOAEL)/Exposure (mg/kg/day)

- Key Inputs/Factors
  - Label/Use Directions
    - e.g., application rate
  - Activity/Amount per day
  - Unit Exposure (dermal and inhalation)
    - Exposure per amount of product handled
    - Use pattern specific values
  - Dermal Absorption
  - Body Weight



# Post-Application Residential Exposure

- Complex compared to handler assessments
- Exposure source characterization
  - e.g., Turf-Transferrable Residue (TTR)
- Behavioral based approaches
  - Index lifestage
  - Dermal contact levels
  - Mouthing rates
  - Breathing Rates
  - Frequency/Duration of Behaviors
  - Types of behavior & how to address





# Post-Application Residential Exposure

$$\frac{\mu g \ chem X}{cm^2} \times \frac{TC - cm^2}{hour} \times \frac{hours \ of \ activity}{day} \div kg \ BW = Exposure \ (mg/kg/d)$$

MOE = Point of Departure (e.g., NOAEL)/Exposure (mg/kg/day)

- Key Inputs/Factors
  - Label/use directions
  - Residue level
    - Deposition on area basis & dissipation kinetics
  - Activity which defines:
    - TC or Transfer Coefficient (dermal rate of contact)
    - Index lifestage (determines if mouthing behavior considered)
  - Exposure Time
  - Dermal Absorption
  - Body Weight



### **SEPA** Aggregate Exposure











### **SEPA** Aggregate Exposure

### FQPA defines "safe" as:

"there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposure and all other exposure for which there is reliable information."

- Combine Routes of Exposure
  - Generally a single compound
  - Common effects across routes
  - Reliable estimates of exposure
  - Avoid overestimate + overestimate + overestimate
- Does not include occupational exposure



# Aggregate Scenarios

### Acute (≤1-day)

 usually dietary food and DW only, occasionally includes refined residential exposures

### Short-term (1-30 days)

food, DW, residential - only done when residential scenarios exist

### Intermediate-term (1-6 months)

 food, DW, residential - only done when residential scenarios exist

### Chronic (6 months - lifetime)

 usually dietary food and DW, occasionally includes residential exposures

### Cancer

food, DW, residential

### **SEPA** Occupational Exposure

• Handlers: those who may be exposed while mixing, loading, and/or applying pesticides



Post-application workers: those who enter previously treated areas to tend/ harvest crops that have been previously treated



### **SEPA** Scenario Based Approach









### **SEPA** Occupational Handlers

$$\frac{\text{Exposure}}{\text{(mg/day)}} = \frac{Application}{Rate} \times \frac{Area}{Treated} \times \frac{Unit}{Exposure}$$

### Key Inputs

- Application Rate:
  - based on the label or usage information (lb ai/Acre)
- Acres treated:
  - standard values from data and surveys (Acres or gallons per day)
- Unit exposure:
  - Exposure per pound of active ingredient handled (e.g., mg/lb ai)
  - Distinct values based on task and level of personal protection
  - Extensive library of values developed through a collaborative multi-governmental and industry effort

# **SEPA** Unit Exposure Example

	The second secon	Pesticide Programs / Health E landler Unit Exposure Surrog			
Scenario	Exposure Route	Personal Protective Equipment (PPE) Level <sup>1</sup>	Data Source <sup>2</sup>	Statistic	Unit Exposure (µg/lb ai)
Mixing / Loading Dry Flowable	Dermal	Single layer, no gloves (A)	AHETF	Mean	227
		Single layer, gloves	AHETF	Mean	51.6
		Double layer, gloves (B)	AHETF	Mean	41.2
		Engineering control (water-soluble packaging)	PHED	"Best fit"	9.8
	Inhalation	No Respirator	AHETF	Mean	8.96
		PF5 (C)	AHETF	Mean	1.79
		PF10 (D)	AHETF	Mean	0.90
		Engineering control (water-soluble packaging)	PHED	"Best fit"	0.24
Applicator, Open Cab Groundboom	Dermal	Single layer, no gloves (A)	AHETF	Mean	78.6
		Single layer, gloves	AHETF	Mean	16.1
		Double layer, gloves (B)	AHETF	Mean	12.6
		Engineering control (Enclosed Cab)	PHED	"Best fit"	5.1
	Inhalation	No Respirator	AHETF	Mean	0.34
		PF5 (C)	AHETF	Mean	0.07
		PF10 (D)	AHETF	Mean	0.03
		Engineering control (Enclosed Cab)	PHED	"Best fit"	0.043

## **\$EPA**

# PPE Types





# **SEPA** Engineering Controls



Closed Loading

Closed Cab Sprayer



# **SEPA** Occup. Post-application

- Exposure occurs from contact with treated areas and crops
  - Varies by type of crop and activity being performed
  - >7000 crop/activity combinations identified







# **SEPA** Occup. Post-application

Exposure 
$$= \frac{DFR \text{ or } TTR}{(\text{mg/day})} \times \frac{TC}{(cm^2/hr)} \times \frac{ET}{(hrs/day)}$$

- Key Inputs
  - Dislodgeable Foliar Residue (DFR) or Turf Transferable Reside (TTR):
    - Residue on foliage that can transfer to a worker's skin
  - Transfer Coefficient (TC)
    - Measure of contact with foliage while performing a specific activity
  - Exposure Time (ET)
    - Amount of time spent performing activity per day
- Risk estimates used to define Restricted Entry Intervals or REIs are key output
  - i.e., time-based exclusions from fields until residues dissipate

# Transfer Coefficient **SEPA** Examples

Crop/Activity Combinations and Recommended TCs							Source Study	
Crop Group	Crop	Crop Height	Foliage Density	Activity	TC	Crop	activity	
Field/row crop, tall	Sweet corn	High	Full	Irrigation	1,900	Potato	irrigation	
Field/row crop, tall	Sweet	High	Full	Scouting	210	Cotton and Tomato	Scouting	
Field/row crop, tall	Sweet corn	High	Full	Detasseling, hand harvesting	17,600	Sweet corn	Hand harvesting	
Vegetable, "root"	Sweet potato	Low	Full	Irrigation	1,900	Potato	Irrigation	
Vegetable, "root"	Sweet potato	Low	Full	Mechanical weeding and harvesting	0	No TC	No TC	
Vegetable, "root"	Sweet potato	Low	Full	Hand weeding	70	Cotton	Hand weeding	



## Risk Characterization

# Risk Assessment gives you a number. Risk Characterization tells what that number means.

We routinely consider (among other factors):

- Data Quality
- Distributional Data
- Interdependencies Between Variables
- Co-Occurrence of Exposure

We also follow EPA Risk Characterization Guidance

# **SEPA** Topical Issues

- Hazard
  - Thyroid, Tox 21, IVIVE
- Epidemiology use in risk assessment
- Exposure
  - Working children, spray drift, volatilization, probabilistic methods

## **SEPA** Antimicrobial Pesticides

- Assessments follow same framework as conventional pesticides.
  - Antimicrobials are defined by claims. If the product label makes antimicrobial claims, the active ingredient is considered an antimicrobial pesticide.
  - Many high production volume (HPV) compounds and/or overlap jurisdiction with FDA and other parts of EPA such as Offices of Air and Water.
  - Supporting data may be from open literature and not from guideline studies.

## **SEPA** Antimicrobial Pesticides

- Occupational and residential exposure scenarios are unique.
  - Janitors, factory and processing facility workers, health care personnel, painters.
    - Task forces such as AEJV and AEATF support AD assessments
  - Cannot mitigate risk by PPE for many occupational and residential uses.
  - End use products for material preservatives don't have pesticide labels informing users of potential exposures.

## **SEPA** Antimicrobial Pesticides

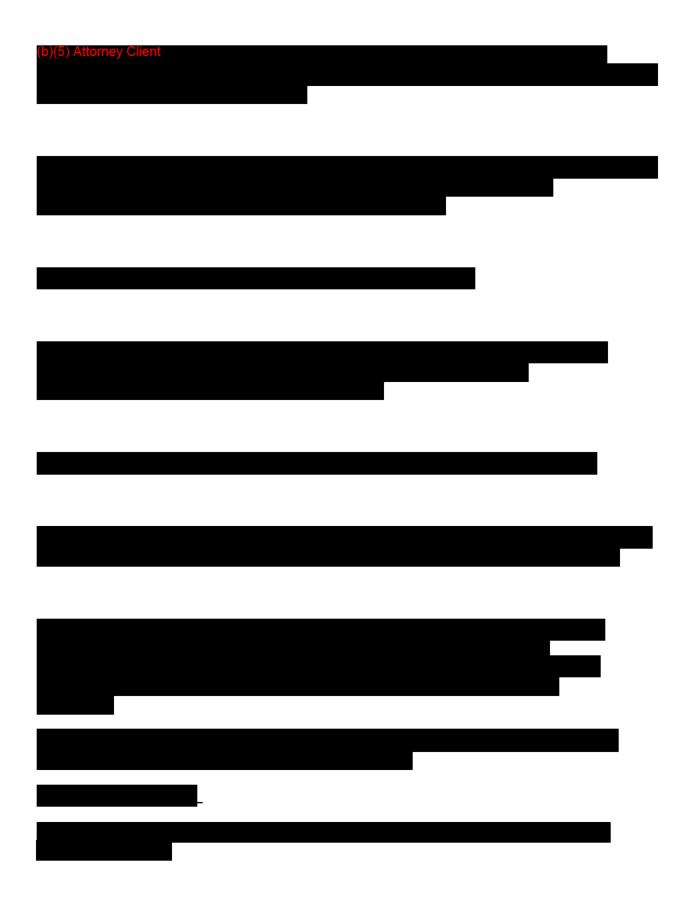
- Dietary exposures:
  - Direct dietary exposures from postharvest and processing rinses.
  - Indirect dietary exposures from transfer from items such as food packaging, countertops and cutting boards.
    - Major issue is the assumption that Potable Water Rinses do not remove 100% of residues.
    - AD is using new models developed with ACC such as Indirect Dietary Residential Exposure Assessment Model (IDREAM) and Food Contact Sanitizing Solutions Model (FCSSM).

## **SEPA** Biopesticides

- Biochemical, Microbial and PIPs
  - Biochemical assessments similar to conventional pesticides with reduced and tiered testing requirements
  - Microbial assessments based on pathogenicity and infectivity hazard endpoint in addition to toxicity
  - Plant-Incorporated Protectants assessment for proteins and nucleic acids expressed in plants using bioinformatics and reduced testing requirements

#### Responses to ESA Questions











# Agenda Meeting on Lead P&CB Survey 4:00 October 13, 2017

#### **Decisions Needed**



#### Discussion

- 1) Background: Statute, Settlement Agreement, Corrective Action Plan with OIG
- 2) Need to revise survey screening question
- 3) Impact on burden
- 4) Possible OMB reactions

#### Potential Revision to Lead Public and Commercial Building Survey

#### Summary

EPA is currently conducting a survey of renovation, repair, and painting (RRP) activities in public and commercial buildings (P&CBs) and the steps taken to control the dust created when lead-based paint (LBP) is disturbed. The survey results will be used in the exposure assessment to determine if these RRP activities create LBP hazards. If there are LBP hazards, the survey results will also be used to support the economic analysis and the development of a rule.

We are midway through the data collection, and the majority of contractors working in P&CBs say they have not worked on LBP. (b)(5) Deliberative Process

#### **Project Background**

TSCA 402(c)(3) directs EPA to revise the lead paint abatement regulations by 1996 to address renovation or remodeling activities that create lead-based paint hazards in target housing and public and commercial buildings (P&CBs).

After EPA issued the 2008 RRP rule for target housing, several lawsuits were filed because, among other things, the rule did not address public and commercial buildings.

In 2009 EPA entered into a settlement agreement which has been amended several times. In the most recent amendment, EPA agreed to propose a rule for P&CBs by March 31, 2017 unless it concluded that renovation activities in pre-1978 P&CBs do not create LBP hazards.

In response to a 2012 Office of Inspector General review of the 2008 RRP rule and the 2010 amendment, OCSPP agreed to conduct a survey of work practices in P&CBs by the end of FY2015.

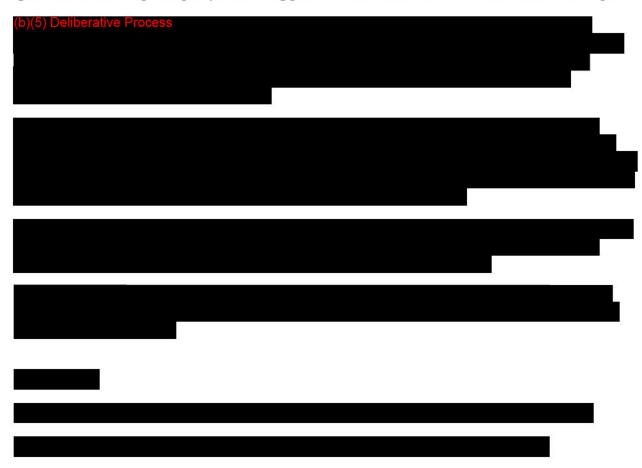
#### Survey Background

A primary purpose of conducting this survey is to provide EPA with data about the extent to which leadsafe work practices (LSWP) are already being used in situations where LBP might be disturbed (i.e., the baseline level of LSWP).

To narrow down the respondents to only those that might need to use LSWP, the questionnaire starts with initial screening questions that ask respondents if they work in P&CB, if they ever disturb more than a de minimis amount of painted surfaces, etc.

We have completed 3 small waves of mailings (5,000 letters each) to solicit participation in the survey, and are in the midst of following up on a large mailing (25,500 letters). A second large mailing (another 25,5000 letters) is planned for November.

The majority of the contractors surveyed so far that passed the screen and completed the full questionnaire are reporting *only* disturbing painted surfaces that do NOT contain lead-based paint.



#### **Approved ICR Burden Estimates**

Questionnaire	Response Type	Estimated Respondent Universe	Per- Respondent Burden (minutes)	Total Respondent Burden (hours)
Contractors	Screening only	1,391	3	70
Contractors	Screening + Full Questionnaire	254	33	140
Lessors and	Screening only	1,972	3	99
Property Managers	Screening + Full Questionnaire	68	8	9
Devilding Occurrents	Screening only	4,720	3	236
Building Occupants	Screening + Full Questionnaire	80	8	10
C C All	Screening only	8,083	-	-
Summary for All Respondents	Screening + Full Questionnaire	402	-	-
Respondents	Total	8,485	-	564



#### Public and Commercial Building Survey Status as of September 28, 2017

Survey Mailing Waves					
Date	Mailing Size	Phone calls			
December 2016	5,000 letters	Completed			
February 2017	5,000 letters	Completed			
June 2017	5,000 letters	Completed			
September 2017	25,500 letters	Underway			
anticipated November 2017	25,500 letters	Planned for November & December			

Screening Survey					
Survey	Web survey	Phone survey	TOTAL SCREENS		
Contractor	273	2889	3162		
Manager	155	1763	1918		
Occupant	101	1565	1666		
TOTAL	529	6217	6746		

Full Survey Completions						
Survey	Web	Phone survey	TOTAL Completes	Target Completes	% Complete	Completes Still Needed
Contractor	72	49	121	254	47.6%	133
Manager	16	27	43	68	63.2%	25
Occupant	36	41	77	80	96.3%	3
TOTAL	124	117	241	402	60.0%	161

#### **Discussion Topics**

IFRANA is pleased to schedule a meeting between key members of its Board of Directors, its staff, and the Environmental Protection Agency. In advance of this meeting, please review this document for information about IFRANA and insight into the association's needs, including new chemicals, TSCA modernization (under the *Frank R. Lautenberg Chemical Safety for the 21st Century Act*/LSCA), and communications with the agency.

#### **About IFRANA**

IFRANA is the principal trade association representing the interests of the fragrance industry in the United States. Our member companies create and manufacture fragrances and scents for home care, personal care, home design, fine fragrance, and industrial and institutional products. IFRANA also represents companies that supply fragrance ingredients, including natural extracts and other raw materials, that are used in perfumery and fragrance mixtures. Recently, several consumer product companies joined IFRANA, which is a testament to the value fragrance offers throughout the supply chain.

These companies are a key engine in our economy, as U.S consumers spend an estimated \$80 billion/year on fragrance dependent products. Further, the fragrance sector supports 720,000 jobs directly and indirectly and 240,000 small businesses.

#### **New Chemicals**

IFRANA appreciates the agency's efforts to reduce the new chemicals backlog. In the fragrance industry, however, new chemical innovation has been completely halted. Fragrance houses that create new chemicals rely on the ability to sell these chemicals to consumer product companies. Consumer product companies will not accept materials with significant new use rules (SNURs). In the context of fragrance new chemicals, the issuance of a "not likely to present an unreasonable risk" finding is rare. Accordingly, SNURs render a new chemical unusable for fragrance companies. New chemicals lose their value and affected companies lose years of R&D and the millions of dollars invested in new chemicals. This system creates a twofold problem for international fragrance houses as (1) new, safe, highly tested chemicals can be (and are being) registered elsewhere in the world and (2) this alters the previously seamless process of near simultaneous registration of new chemicals in the U.S. and in Canada. The congressional intent behind the LSCA focused on safety, businesses, and innovation; the current processing of new chemicals undermines these priorities.

<u>Request</u>: Our primary objective for this meeting is to communicate that the fragrance industry cannot continue to operate under the current PMN process; processing new chemical requests using SNURs cannot become the status quo. IFRANA asks that this message be communicated within the agency. The fragrance industry suggests a workable process for the registration of new chemicals without the overuse of SNURs. IFRANA and its members are willing to be flexible under

October 26, 2017 Meeting
IFRANA – the fragrance industry association
Page 2 of 3

this process, especially as it pertains to timeline, thresholds, data requests, etc. If the agency is willing to implement a process that allows new chemicals to proceed without SNURs, our members are happy to cooperate as the agency deems appropriate, including more conversations between companies and EPA staff.

#### TSCA Modernization/LSCA Implementation

The fragrance industry commends EPA for its implementation efforts thus far and for its increased willingness to hold public meetings and webinars and to aid stakeholders. On the whole, the fragrance industry would like to communicate more with the agency on the following topics:

- IFRANA looks forward to the upcoming prioritization public meeting and would appreciate any information about the agency's "pre prioritization" process and any potential reporting requirements for chemical processors. Our members, particularly SMEs, are interested in learning what information the agency will want and when.
- IFRANA appreciates EPA's efforts to put forth Q&A information on the inventory reset and guidance regarding animal testing; our members would be interested in hearing a status update on these documents.
- As the agency prepares for chemical data reporting (CDR) in 2020 and works to implement the LSCA, IFRANA encourages the use of voluntary data submissions whenever possible and believes it can be a resource to EPA.
- IFRANA submitted comments on the pending fees rule. As a summary, please consider the following:
  - PMN fees should not be substantially increased beyond the inflation adjusted version of \$2,500;
  - EPA should not tie fees to uses;
  - EPA should establish volume based fees;
  - EPA should note charge fees for CBI claims; and
  - o EPA should not attempt to model its fee authority on the pesticide or drug models.
- IFRANA has also submitted comments related to the reconsideration of the "small business definition." We would encourage this definition to be expanded (both in the context of fees and reporting requirements) and support collaboration with the Small Business Administration on this issue.

<u>Request</u>: The industry asks for increased transparency and an open dialogue with EPA, specifically regarding prioritization and voluntary data submissions. As the agency proceeds with implementing final rules and drafting upcoming rules, IFRANA requests stakeholder engagement, careful consideration of fees, and a robust small business definition.

October 26, 2017 Meeting IFRANA – the fragrance industry association Page 3 of 3

#### A Resource for the Agency

IFRANA has worked with the agency and with its allied trades to improve and advance EPA's Safer Choice program. While the fragrance industry is not calling for an overhaul of the program, we hope to be a resource to the agency as issues arise. Similarly, we applaud Administrator Pruitt's decision to reinstate the Smart Sectors program to work with industry leaders on regulatory issues that affect certain sectors. IFRANA's membership includes upstream and downstream companies and we are happy to inform the agency on chemical specific issues.

<u>Request</u>: Please contact IFRANA, especially if any developments occur with the Safer Choice program. IFRANA is eager to participate in the Smart Sectors program, and is willing to offer any additional insight.



IFRANA is the principal trade association representing the U.S. fragrance industry. Our members manufacture scents used in home care, personal care, fine fragrance, home design, industrial, and institutional products. IFRANA member companies also supply fragrance ingredients—such as essential oils and other raw materials—used in perfumery and fragrance mixtures. IFRANA represents a variety of companies engaged in the business of fragrance, including multi-national companies, medium-sized enterprises, and artisanal fragrance houses.



The fragrance industry operates through a business-to-business model. Fragrance companies source and develop aroma materials that their perfumers carefully blend to create final scents. These proprietary scent mixtures are sold to consumer product companies and incorporated into finished products. The creation, supply, and consumption of fragrance technologies generates wealth, jobs and public benefits throughout the country. Our ability to contribute to the U.S. economy is predicated on the protection of our trade secrets.







IFRANA celebrates the creative artistry of its members and advances intellectual property protections that support the safety, sustainability and integrity of scented products.

Learn more at ifrana.org



Experience more at fragrancesnotes.org

































































































































#### 10/26/17 IFRANA Meeting Participants

Participant	Title	Company	Employees
Farah Ahmed	President & CEO	IFRANA	
Joy Atkinson	President, Body	Firmenich	Princeton, NJ = 1056
es es es es es	and Home Care,	#1 e20	Newark, NJ = 104
	North America		St. Louis, MO = 98
	State of the Artist State of Bure scale (The Artist State of Artist Artist State of Artist Sta		New Ulm, MN = 103
			Lakeland, FL = 150
			New York, NY = 150
	TV		Anaheim, CA 110
Bob Bedoukian	President	Bedoukian	Danbury, CT – 76
		Research	
Shawn Blythe	Vice President,	International	Union Beach, NJ = 255
	Global Regulatory	Flavors &	Hazlet, NJ = 287
	Affairs	Fragrances	South Brunswick, NJ = 452
		(IFF)	Carrollton, TX = 108
			Jacksonville, FL = 90
			New York, NY = 239
			Chicago, IL = 1
			Philadelphia, PA = 285
			Clifton, NJ = 45
			Keyport, NJ = 31
			San Bernardino, CA = 6
Karen Manheimer	Vice President,	Kerry	WI (US Corporate HQ + R&D Flavors):
	Natural Products;	Ingredients &	~800
	IFRANA Treasurer	Flavours	
			Clark, NJ (fragrance raw materials):
			195 (+~150 / 15 months)
Amanda Nguyen	Director,	IFRANA	
	Government		
	Affairs & Legal		
Dan Renberg	Partner	Arent Fox	
Steve Tanner	President;	Arylessence,	~150 in Marietta, GA
	IFRANA Chairman	Inc.	
<b>Bob Weinstein</b>	President:	Robertet U.S.	300 in
	IFRANA Vice		Piscataway & Mount Olive, NJ
	Chairman		

#### TSCA as Gap-Filler / Deference to Other Statutes

#### **Questions Presented**



#### **Summary of Pertinent TSCA Provisions**

- Sec. 6(b)(4)(F)—Requires, among other things, that a risk evaluation integrate and assess
  available information on hazards and exposures for the conditions of use; not consider costs or
  other non-risk factors; take into account as applicable duration, intensity, frequency and
  number of exposures; and describe the weight of the scientific evidence for the identified
  hazard and exposure.
- Sec. 9(a)—Establishes an inter-agency referral process applicable when the Administrator makes
  an unreasonable risk finding and determines, in his discretion, that such risk may be prevented
  or reduced to a sufficient extent by action taken by another federal agency. Once referral
  occurs, EPA may not take any action under secs. 6(a) or 7 while the other agency considers the
  risks in the time period specified by the Administrator. If the other agency does not act, then
  the Administrator shall initiate or complete the sec. 6(a) or 7 action.
- Sec. 9(b)—Establishes an intra-agency coordination process applicable when the Administrator determines that a risk associated with a chemical could be eliminated or reduced to a sufficient extent by EPA actions under other federal laws within the Administrator's jurisdiction. Provides that the Administrator shall use such other authorities to protect against the risk unless he determines, in his discretion, that it is in the public interest to protect against such risk by actions taken under TSCA. In making a public interest determination, the Administrator must consider the relevant risks and a comparison of the costs and efficiencies of taking action under TSCA versus the other statute.
- Sec. 26(h), (i), (k)—Requires that science-based decisions under sec. 6 use information/ methods/etc. consistent with best available science; be based on the weight of the scientific evidence; and take into consideration reasonably available information.

#### TSCA Legislative History (1976)

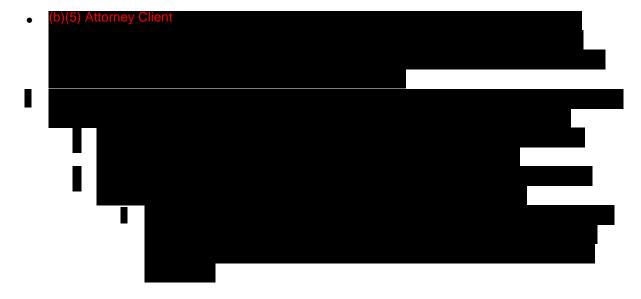
- Senate and House committee reports describe TSCA as filling the following "gaps" that existed in the protections provided by other statutes and regulations:
  - o premarket review;
  - direct regulation of chemicals (as opposed to discharges/emissions, regulation of which Congress believed may sometimes be a less efficient way to manage hazards than limiting use of the chemical in the first instance);
  - consideration of all the risks, including cumulative impact of all sources of exposure; and

- o collection of test data. S. Rep. No. 94-698 at 1-2; H. Rep. No. 94-1341 at 6-7.
- The Senate report explains: "While individual agencies may be authorized to regulate occupational, environmental, or direct consumer hazards with respect to a chemical substance, there is no agency which has the authority to look comprehensively at the hazards associated with the chemical. Existing authority allows the agencies to only look at the hazards within their jurisdiction in isolation from other hazards associated with the same chemical. The bill would grant [EPA] the authority to look at the hazards in total." S. Rep. No. 94-698 at 2.
- The Conference Report explains that sec. 9 is intended "to assure that overlapping or duplicative regulation is avoided while attempting to provide for the greatest possible measure of protection to health and the environment." S. Rep. No. 94-1302 at 84.

#### <u>Lautenberg Act Legislative History (2015-16)</u>

- The House Report states that the intent of the amendments is to "reinforce TSCA's original purpose of filling gaps in Federal law," citing language in sec. 9(b)(2) to "help the Administrator decide whether using TSCA" is in the public interest particularly when disposal of a chemical substance is already regulated under RCRA. H. Rep. No. 114-176 at 28.
- Debate in the House among Republican members reflects their understanding that "Congress' intent is to avoid duplicative regulation through the TSCA law." 162 Cong. Rec. at H3028.
- The statement from the Senate Democratic members explains that the changes made in the Lautenberg Act as a whole make TSCA unable to "be construed as a 'gap-filler' statutory authority of last resort" except under the express procedures in sec. 9(a). 162 Cong. Rec. at S3517. It states that the language in sec. 9(b)(2) only applies when the Administrator has determined another statute could reduce the risk, and that sec. 9(b) "allows the Administrator substantial discretion to use TSCA nonetheless, and certainly does not reflect that TSCA is an authority of last resort in such cases."
- Senator Vitter stated that, under section 9(b), EPA should use other authorities, such as RCRA, to address disposal risks. S3522 col. 1.

#### **Considerations for Risk Evaluations**





# Briefing on Antibiotics for OCSPP Deputy Assistant Administrators

November 15, 2017

### **OPP Team Members**

- RD: Fatima Sow, Heather Garvie, Hope Johnson, Cynthia Giles-Parker, Rosanna Louie-Juzwiak, Tawanda Maignan, Andrea Conrath, Andy Ertman, Tamica Cain
- HED: Kelly Lowe, Linda Taylor, Peter Savoia, Michael Metzger, Christina Swartz, Linnea Hansen, William Drew, Gerad Thornton, Sarah Dobreniecki, Ume Hassan, Kristin Rickard
- EFED: Andrew Shelby, Brian Kiernan, Monica Wait, Mark Corbin, Dana Spatz, Katherine Stebbins, Jim Hetrick, Karen Milians, Thomas Steeger, Jean Holmes
- BEAD: Tara Chandgoyal, Leonard Yourman, Colwell Cook, Monisha Kaul
- ARRT: Samantha Collins, Tara Chandgoyal, John Kough, Susan Jennings
- IO: Susan Jennings
- PRD: Matthew Manupella, Kevin Costello, Cathryn Britton
- FEDERAL PARTNERS: CDC, FDA, USDA
- OGC: Erin Koch

## Antibiotics as Agricultural Use Bactericides

• There are 3 antibiotic active ingredients currently registered for agricultural use in the United States:

Active Ingredient	Class of Compound	Year Registered	Registered Uses
Streptomycin	aminoglycoside	1955	<ul> <li>Pome fruit, beans, greenhouse seedlings (celery, pepper, tomato), potato seed piece, tobacco, ornamental, homeowner garden</li> <li>Current citrus Section 18 use approved in Florida through 12/31/2017</li> </ul>
Oxytetracycline	tetracycline	1974	<ul> <li>Apple, pear, peach, nectarine, nonagricultural uses (forest tree injection, ornamentals, non crop bearing trees, shrubs, palms</li> <li>Current citrus Section 18 use approved in Florida through 12/31/2017</li> </ul>
Kasugamycin	aminoglycoside	2014	<ul> <li>Pome fruit group (time-limited registration expiring 12/31/2018)</li> </ul>

- Both Streptomycin and Kasugamycin are also approved for use by PMRA (Canada) for certain uses.
- Of these active ingredients, both streptomycin and oxytetracycline also have human and animal drug uses approved with the Federal Drug Administration (FDA). Kasugamycin is not used for human or veterinary medical purposes.

# Currently Pending New Uses with the Office of Pesticide Programs (OPP)

#### Streptomycin

- 1 action submitted by The Interregional Research Project No. 4 (IR-4)/Geologic Corporation/Agrosource Inc on grapefruit, tomato (field plus expanded greenhouse use), and conversion of pome fruit crop group 11 to 11-10.
- 1 petition submitted by Geologic Corporation/Agrosource Inc. on citrus crop group 10-10

#### Oxytetracycline

- 1 petition submitted by Geologic Corporation, Agrosource Inc. for uses on citrus crop group 10-10
- 1 petition submitted by Nufarm Americas, Inc. on citrus crop group 10-10\*
- 1 petition submitted by Nufarm Americas, Inc. on cherry\*
  - \*these petitions are on a later review schedule

#### Kasugamycin

 1 petition submitted by IR-4, Arysta LifeScience North America LLC for uses on walnut and cherry subgroup 12-12a

## Registration Review

- Only streptomycin and oxytetracycline are in this round of registration review; kasugamycin was registered in 2014
- Assessments from HED and EFED are complete, ARRT assessment pending
- All assessments are scheduled to be published in June 2018
- Proposed Interim Decisions scheduled to be completed in March 2019, with Interim Decisions scheduled to be completed in September 2019

## The Rationale for Antibiotic Use in Agriculture

- There are few registered alternatives for most bacterial infections in crops. Different modes of action (MOAs) would help reduce the potential for resistance to develop in any current conventional/biopesticide tools approved.
- Huanglongbing (HLB), also known as citrus greening disease, is one of the world's most serious citrus diseases, with no known cure.
- Walnut growers/groups have reached out to the Agency over the past year greatly supporting the proposed use for kasugamycin on walnut to control walnut blight and have requested an expedited review.
- Over the past 10 years, numerous sections 18 emergency exemptions have been issued to various States for the use of antibiotics (kasugamycin, gentamycin, oxytetracycline, and streptomycin) on pome fruit and citrus to address different diseases such as fire blight, citrus canker and HLB.

# How Antibiotic Assessments Differ from Conventional Pesticide Assessments

- Conventional pesticide assessments comprise of:
  - Human health risk assessment
    - Toxicology, Occupational Exposure, Residue Chemistry
  - Ecological risk assessment
    - Environmental fate and effects
  - Benefits review
    - Efficacy, alternatives comparison
- In addition to these, antibiotic assessments <u>also</u> include:
  - Antibiotic resistance review based on FDA's Guidance to Industry #152 assessment with the addition of active ingredient specific isolate study review
  - Federal Partner consultation with the FDA/CDC/USDA on our antibiotic resistance reviews
  - Review of Resistance Management proposal from the Registrant including label language review, efficacy, and review of proposals for educational materials/stewardship plan

# How Antibiotic Assessments Differ from Conventional Pesticide Assessments (Cont'd)

• Generally speaking, the antibiotics registered for agricultural use have no traditional human health risk assessment concerns and few ecological risk concerns. Instead, our concerns come from the possibility of agriculture bactericide use contributing to antibiotic resistance developing in humans and plants

# Antibiotic Resistance Effects

- At least 2 million people acquire serious antibiotic-resistant infections each year
  - At least 23,000 people die each year as a direct result of these antibiotic-resistant infections
- Almost 250,000 people each year require hospital care for C. difficile infections
  - At least 14,000 people die each year in the United States from *C. difficile* infections
- Antibiotic-resistant infections add costs to the already overburdened U.S. healthcare system
  - Antibiotic-resistant infections usually require long, costly treatments, extended hospital stays
- Total economic cost of antibiotic resistance to the U.S. economy estimates vary but have ranged as high as \$20 billion in excess direct healthcare costs

# How Resistance Develops

- Bacteria will inevitably find ways of resisting antibiotics
- Bacteria may adapt to become resistant to an antibiotic by
  - Restricting access of the antibiotic to the cell or using pumps to keep antibiotic drugs from entering
  - Destroying the antibiotic by using enzymes to break down the antibiotic drug and make it ineffective
  - Changing the antibiotic by using enzymes to alter the antibiotic drug so that it loses its
    effectiveness
  - Developing different and new processes to get around those disrupted by the antibiotics
- Often, resistance genes are within plasmids, pieces of DNA that can move between bacterial species
  - Enables the spreading of resistance from one bacteria to another
- CDC believes aggressive action is needed now to keep new resistance from developing and to prevent the resistance that already exists from spreading

# Antibiotic Resistance Review Team (ARRT) Assessment

- Qualitative risk assessment evaluating the probability of antibiotic resistance in microbes of human health concern based on FDA's 152 guidance to industry for antibiotic use in food animals, with modifications appropriate to agricultural chemicals.
- Assessment categories: release, exposure, consequence.
- These three elements provide an overall qualitative risk estimate

## ARRT Assessment Criteria

RELEASE ASSESSMENT

(rating scale: low, medium, or high)

Product chemistry, Resistance mechanisms in microbes, Transfer of resistance, Selection Pressure

EXPOSURE ASSESSMENT

(rating scale: low, medium, or high)

Food contamination of crop, Food Commodity Consumption, Acreage treated

CONSEQUENCE ASSESSMENT

(rating scale: important, highly important, critical)

Rating of Clinical Importance of Antibiotic

RISK ESTIMATION

(rating scale: low, medium, high)

Integrates the components of the 3 assessments into an overall qualitative conclusion

# ARRT Assessment Outcomes Streptomycin- Citrus Crop Group 10-10

## Release rating: high

• Clinical microbe resistance common & mobile; interaction with environmental isolates; expanded acreage

### Exposure rating: medium

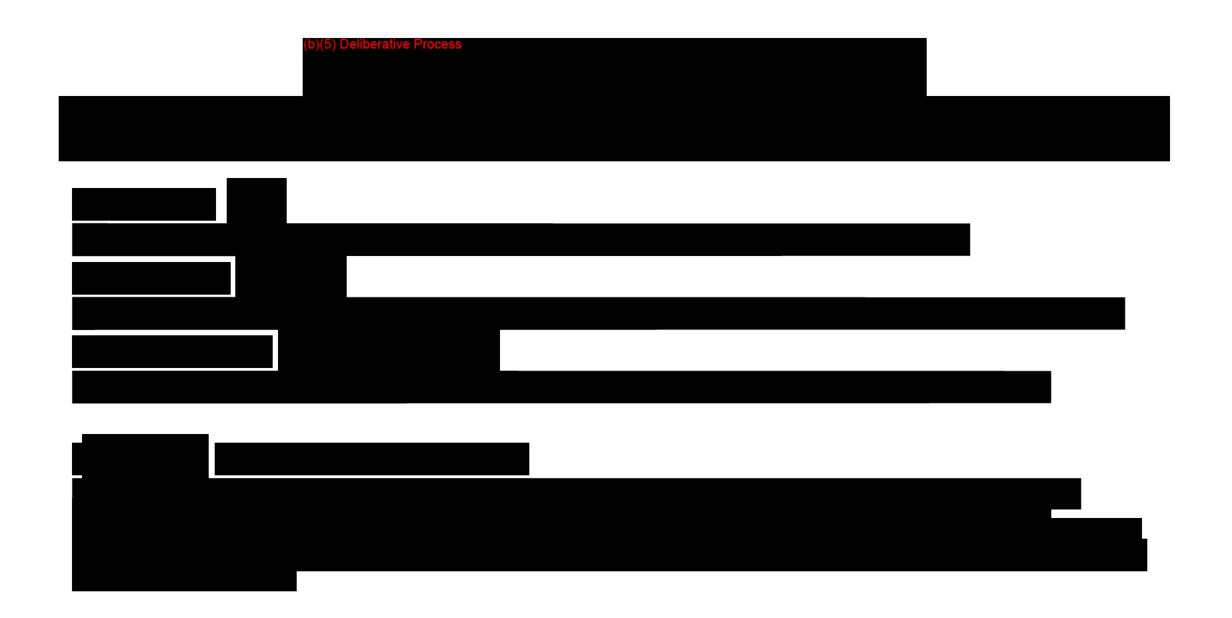
 Increased acreage, citrus food commodity being consumed is high; contamination and food poisoning incidents are low

### Consequence rating: highly important

• Member of aminoglycoside group, currently used in treatment of bacterial diseases and infections

# "Medium" qualitative risk estimation rating

Uncertainties: information is lacking on presence of bacteria associated with food borne disease in citrus orchards and the movement of traits from the target and epiphytic bacteria to bacteria of concern for human health. For the exposure assessment, data on the actual level of contamination with bacteria of human concern on citrus and citrus commodities are not available.



# ARRT Assessment Outcomes-Oxytetracycline- Citrus Crop Group 10-10

## Release rating: high

 Resistance in clinical microbes common & mobile; interactions with environmental isolates; expanded acreage

### Exposure rating: medium

 Increased acreage, citrus food commodity consumption high; contamination of citrus and food poisoning incidents are low

### Consequence rating: highly important

• Member of tetracycline group, currently used in treatment of bacterial diseases and infections

"Medium" qualitative risk estimation rating due to greatly expanded acreage for Citrus canker and Citrus Greening

Uncertainties: limited information for resistance selection & mobility associated with environmental isolates. No robust information in public literature on rate of transfer for tetracycline resistance.

# ARRT Assessment Outcomes-Kasugamycin- Walnut, Cherry Subgroup 12-12a

### Release rating: low

 Low selection for cross resistance to other antibiotics; not effective against human pathogenic species

### Exposure rating: low

Level of food commodity contamination low but variable; food poisoning incidents low

### Consequence rating: important

• Lowest risk rating, field data shows no change in resistance frequency to other aminoglycosides in presence of kasugamycin resistance in bacteria; no clinical uses, different binding site in bacterial protein translation

### Overall risk estimation: "Low"

- Lab data on lack of cross-resistance is confirmed by field monitoring data to date.
- Uncertainties: No definitive data to cite for the resistance transfer endpoint. Information lacking on kasugamycin susceptibility for the range of bacteria associated with food borne incidents in crops proposed. Rating could change if agricultural use does co-select for resistance to other clinically important antibiotics in the future.

# Stewardship of Antibiotics

- Managing antibiotic resistance is critical to keeping antibiotics working
- OPP assessments consider resistance in the bacteria causing the plant disease and the potential contribution to antibiotic-resistant diseases in humans
- Human pathogens and plant pathogens may exist together, so that resistance may develop in human pathogens as a result of antibiotic use on crops
  - Pathogens rarely share the same hosts
- For pesticides, resistant species in or on food, the skin of workers, or indirectly through the environment or clothing can spread resistance.
- By minimizing these three routes of exposure, EPA hopes to minimize the growth or spread of resistant microbes on humans or on the crop.

# Federal Response To Antibiotic Resistance

- Other agencies (CDC, FDA, USDA) work in their areas of expertise
- CDC cites "Improving Antibiotic Prescribing/Stewardship" as one of its Four Core Actions to Fight Resistance
- FDA is committed to antimicrobial stewardship, fostering stewardship and assessing impact of intervention strategies in veterinary settings
- USDA funds research to study the role of agriculture in antimicrobial resistance and identifying alternative strategies to mitigate antimicrobial resistance in the food chain

# EPA's Response to Antibiotic Resistance

- EPA shares USDA's goal of "reducing potential negative impacts from the use of antibiotics, and identifying alternative strategies for mitigating [antibiotic resistance] in the food chain."
- EPA believes that the management of pesticide resistance development is an important part of sustainable pest management
- In support of these goals, EPA is assessing the potential development of antibiotic resistance as an adverse effect under FIFRA.

# Federal Partner Consultation



# Ongoing International Work

- Codex Alimentarius Commission (Codex) is a Joint FAO/WHO Food Standards Program that harmonizes international food safety standards and helps facilitates trade.
- In December 2016, Codex established the Task Force on Antimicrobial Resistance (TFAMR). The objective of TFAMR is to establish science-based guidance on the human health risk associated with antimicrobial resistance in different areas of use of antimicrobials, including veterinary applications, plant protection and food processing.
- TFAMR recently issued a data call on antimicrobials used in plant protection and has requested -- through the Codex Committee on Pesticide Residues -- guidance on data sources that characterize use practices of pesticides that may contribute to antimicrobial resistance.

# Benefits of Antibiotics for Plant Uses

- OPP assesses the benefits of pesticides to the user and considers target pests and alternative control methods
- The benefits of new uses of antibiotics can vary depending on several factors
  - Especially, the ability of the grower to acceptably manage a disease by other methods (including registered pesticides)
  - Severity and incidence of the disease
- Bacterial diseases of crops can be difficult to manage
  - Occur sporadically and depend on weather conditions, especially humidity, temperature, and wetness
- Generally, antibiotics can reduce effects of, but do not cure, plant disease
  - For citrus, antibiotics would be most effective when applied to replacement trees prior to development of severe disease symptoms

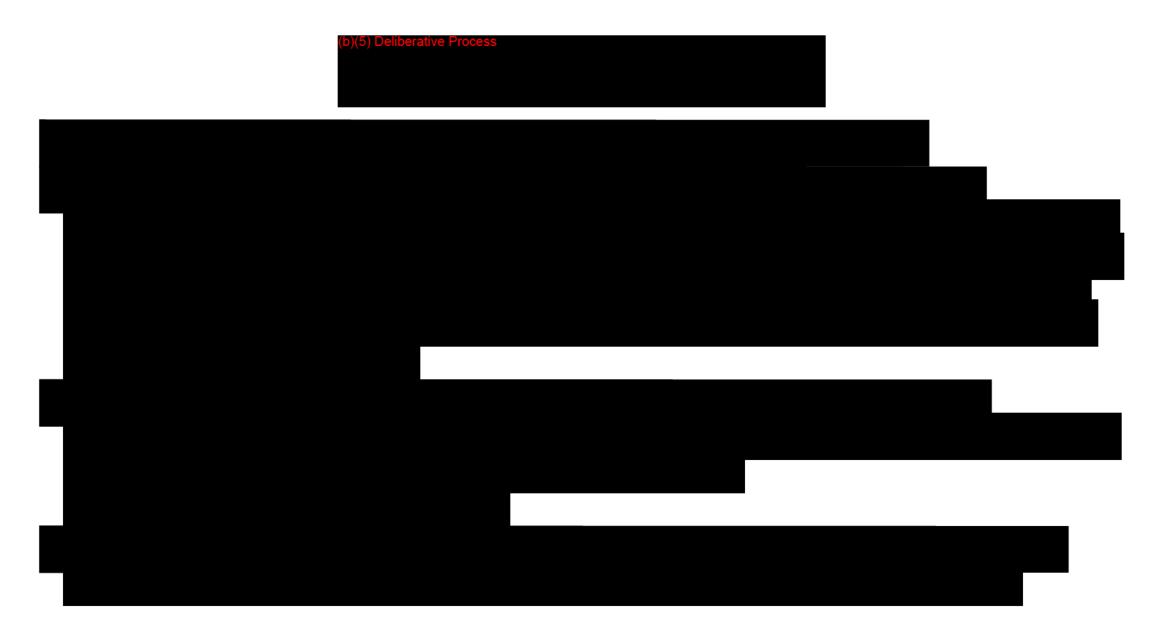


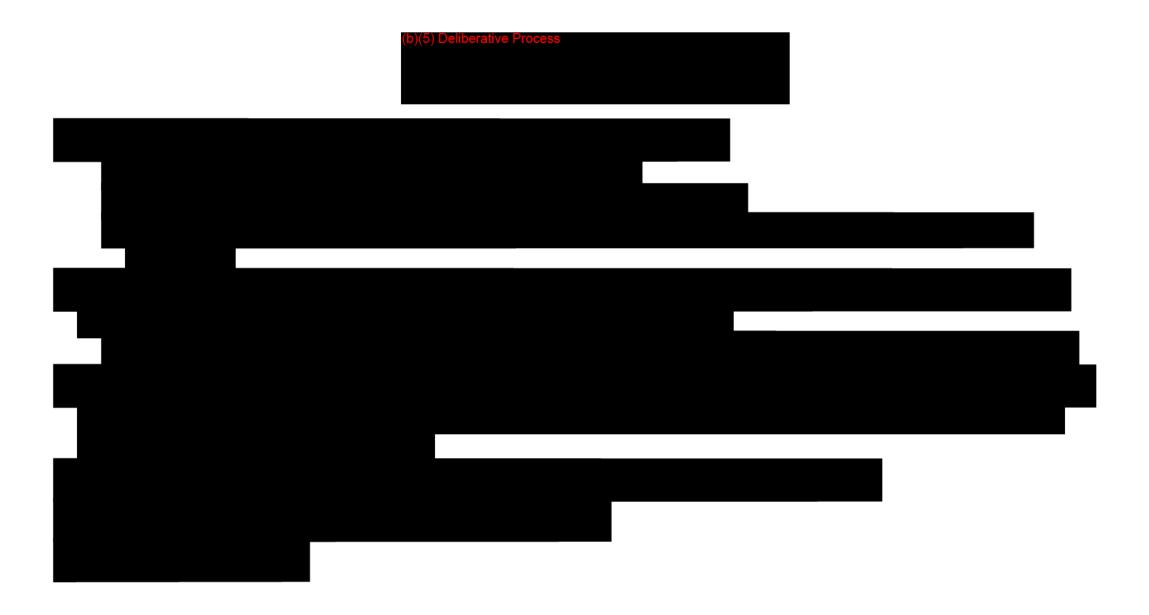
# Kasugamycin, Oxytetracycline and Streptomycin: A Comparison











# Current PRIA due dates

Active Ingredient	Petitioner/Registrants	Proposed Uses	Current PRIA due date
Oxytetracycline	Agrosource Inc./Geologic Corp.	Citrus crop group 10-10	2/13/2018
	Nufarm Americas Inc.	Citrus crop group 10-10	1/18/2018*
	Nufarm Americas Inc.	cherry	5/9/2018*
Streptomycin	IR-4/Agrosource Inc./Geologic Corp.	Grapefruit/tomato/pome fruit crop group conversion	4/3/2018
	Agrosource Inc./Geologic Corp.	Citrus crop group 10-10	4/3/2018
Kasugamycin	IR-4/Arysta LifeScience North America Inc.	Walnut, cherry subgroup 12- 12a	1/16/2018

<sup>\*</sup>The Nufarm America's Inc. petitions will be renegotiated to later in 2018 (end of FY2018).

#### TSCA SCOPE

Objective: To discuss the nexus between TSCA and other statutes.

Date: 4:15pm, Friday, December 8, 2017

Location: 3371 EPA East

Conference Line: Call in 1(6) (6)

**Meeting Materials:** 

TSCA as a Gap Filler

- TSCA Section 2, 3, 6 & 9 and Rule Provisions, re: Risk Evaluation & Unreasonable Risk.
- Risk Evaluation Process and Timeline and First 10 Chemicals
- Example of Conceptual Models:
  - o Methylene Chloride (industrial and commercial)
  - Methylene Chloride (environmental release & wastes)
  - o Carbon Tetrachloride

#### Agenda

- Welcome and Introductions (AII)
- (b)(5) Deliberative Process
- Overview of OPPT Risk Evaluation Approach and Conceptual Models
- (b)(5) Deliberative Process
- Wrap Up and Next Steps (OCSPP)

#### TSCA as Gap-Filler / Deference to Other Statutes

#### **Questions Presented**

(b)(5) Deliberative Process

#### **Summary of Pertinent TSCA Provisions**

- Sec. 6(b)(4)(F)—Requires, among other things, that a risk evaluation integrate and assess available information on hazards and exposures for the conditions of use; not consider costs or other non-risk factors; take into account as applicable duration, intensity, frequency and number of exposures; and describe the weight of the scientific evidence for the identified hazard and exposure.
- Sec. 9(a)—Establishes an inter-agency referral process applicable when the Administrator makes an unreasonable risk finding and determines, in his discretion, that such risk may be prevented or reduced to a sufficient extent by action taken by another federal agency. Once referral occurs, EPA may not take any action under secs. 6(a) or 7 while the other agency considers the risks in the time period specified by the Administrator. If the other agency does not act, then the Administrator shall initiate or complete the sec. 6(a) or 7 action.
- Sec. 9(b)—Establishes an intra-agency coordination process applicable when the Administrator determines that a risk associated with a chemical could be eliminated or reduced to a sufficient extent by EPA actions under other federal laws within the Administrator's jurisdiction. Provides that the Administrator shall use such other authorities to protect against the risk unless he determines, in his discretion, that it is in the public interest to protect against such risk by actions taken under TSCA. In making a public interest determination, the Administrator must consider the relevant risks and a comparison of the costs and efficiencies of taking action under TSCA versus the other statute.
- Sec. 26(h), (i), (k)—Requires that science-based decisions under sec. 6 use information/ methods/etc. consistent with best available science; be based on the weight of the scientific evidence; and take into consideration reasonably available information.

#### TSCA Legislative History (1976)

- Senate and House committee reports describe TSCA as filling the following "gaps" that existed in the protections provided by other statutes and regulations:
  - o premarket review;
  - direct regulation of chemicals (as opposed to discharges/emissions, regulation of which Congress believed may sometimes be a less efficient way to manage hazards than limiting use of the chemical in the first instance);
  - consideration of all the risks, including cumulative impact of all sources of exposure; and

- o collection of test data. S. Rep. No. 94-698 at 1-2; H. Rep. No. 94-1341 at 6-7.
- The Senate report explains: "While individual agencies may be authorized to regulate occupational, environmental, or direct consumer hazards with respect to a chemical substance, there is no agency which has the authority to look comprehensively at the hazards associated with the chemical. Existing authority allows the agencies to only look at the hazards within their jurisdiction in isolation from other hazards associated with the same chemical. The bill would grant [EPA] the authority to look at the hazards in total." S. Rep. No. 94-698 at 2.
- The Conference Report explains that sec. 9 is intended "to assure that overlapping or duplicative regulation is avoided while attempting to provide for the greatest possible measure of protection to health and the environment." S. Rep. No. 94-1302 at 84.

#### Lautenberg Act Legislative History (2015-16)

- The House Report states that the intent of the amendments is to "reinforce TSCA's original purpose of filling gaps in Federal law," citing language in sec. 9(b)(2) to "help the Administrator decide whether using TSCA" is in the public interest particularly when disposal of a chemical substance is already regulated under RCRA. H. Rep. No. 114-176 at 28.
- Debate in the House among Republican members reflects their understanding that "Congress' intent is to avoid duplicative regulation through the TSCA law." 162 Cong. Rec. at H3028.
- The statement from the Senate Democratic members explains that the changes made in the Lautenberg Act as a whole make TSCA unable to "be construed as a 'gap-filler' statutory authority of last resort" except under the express procedures in sec. 9(a). 162 Cong. Rec. at S3517. It states that the language in sec. 9(b)(2) only applies when the Administrator has determined another statute could reduce the risk, and that sec. 9(b) "allows the Administrator substantial discretion to use TSCA nonetheless, and certainly does not reflect that TSCA is an authority of last resort in such cases."
- Senator Vitter stated that, under section 9(b), EPA should use other authorities, such as RCRA, to address disposal risks. S3522 col. 1.

#### **Considerations for Risk Evaluations**



(b)(5) Deliberative Process	

#### Prepared by Environmental Defense Fund based on the text of H.R. 2576, the Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act (June 22, 2016)

Track changes in this version reflect amendments to the Toxic Substances Control Act made by H.R. 2576 as passed by the full House of Representatives on May 24, 2016, and by the full Senate on June 7, 2016, and signed into law by the President on June 22, 2016. Bill Sections 20 ("No Retroactivity") and 21 ("Trevor's Law") are included at the end but not integrated, as they do not amend TSCA.

Note: In several sections, the bill amends TSCA by striking and replacing entire sections or subsections. Where possible, the marked changes below show the amendments integrated with a greater level of detail (to the level of specific words and phrases). In a few places text is marked as having been moved because a provision in the original now appears in a new location, even if the text has changed to some degree.

#### TOXIC SUBSTANCES CONTROL ACT1

[As Amended Through P.L. 114-182, Enacted June 22, 2016]

#### TITLE I—CONTROL OF TOXIC SUBSTANCES

#### SECTION 1. SHORT TITLE AND TABLE OF CONTENTS.

This Act may be cited as the "Toxic Substances Control Act".

#### TABLE OF CONTENTS

#### TITLE I—CONTROL OF TOXIC SUBSTANCES

Sec. 1.	Short title and table of contents.
Sec. 2.	Findings, policy and intent.
Sec. 3.	Definitions.
Sec. 4.	Testing of chemical substances and mixtures.
Sec. 5.	Manufacturing and processing notices.
Sec. 6.	Prioritization, risk evaluation, and Rregulation of hazardous chemical substances and mixtures.
Sec. 7.	Imminent hazards.
Sec. 8.	Reporting and retention of information.
Sec. 9.	Relationship to other Federal laws.
Sec. 10.	Research, development, collection, dissemination, and utilization of <u>informationdata</u> .
Sec. 11.	Inspections and subpoenas.
Sec. 12.	Exports.
Sec. 13.	Entry into customs territory of the United States.
Sec. 14.	Confidential information <del>Disclosure of data</del> .
Sec. 15.	Prohibited acts.
Sec. 16.	Penalties.
Sec. 17.	Specific enforcement and seizure.
Sec. 18.	Preemption.

Sec. 28. State programs.

#### SEC. 2. FINDINGS, POLICY, AND INTENT.

#### (a) FINDINGS.—The Congress finds that—

National defense waiver.

Administration of the Act.

Development and evaluation of test methods.

Employee protection. Sec. 24. Employment effects.

Sec. 19. Judicial review. Sec. 20. Citizens' civil actions. Sec. 21. Citizens' petitions.

Sec. 22.

Sec. 23.

Sec. 25. Sec. 26.

Sec. 27.

<sup>1</sup> The Toxic Substances Control Act (15 U.S.C. 2601–2692) consists of Public Law 94–469 (Oct. 11, 1976; 90 Stat. 2003) and the amendments made by subsequent enactments.

- (1) human beings and the environment are being exposed each year to a large number of chemical substances and mixtures.
- (2) among the many chemical substances and mixtures which are constantly being developed and produced, there are some whose manufacture, processing, distribution in commerce, use, or disposal may present an unreasonable risk of in- jury to health or the environment; and
- (3) the effective regulation of interstate commerce in such chemical substances and mixtures also necessitates the regulation of intrastate commerce in such chemical substances and mixtures.
- (b) POLICY.—It is the policy of the United States that—
  - (1) adequate <u>datainformation</u> should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such <u>datainformation</u> should be the responsibility of those who manufacture and those who process such chemical substances and mixtures;
  - (2) adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards; and
  - (3) authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.
- (c) INTENT OF CONGRESS.—It is the intent of Congress that the Administrator shall carry out this Act in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes as provided to take under this Act.

  [15 U.S.C. 2601]

#### SEC. 3. DEFINITIONS.

#### As used in this Act:

(3) The term 'conditions of use' means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

### SEC. 6. <u>PRIORITIZATION, RISK EVALUATION, AND REGULATION OF HAZARDOUS</u>-CHEMICAL SUBSTANCES AND MIXTURES.

(a) SCOPE OF REGULATION.—If the Administrator finds that there is a reasonable basis to conclude determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents, or will present an unreasonable risk of injury to health or the environment, the Administrator shall by rule, and subject to section 18, and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary so that the chemical substance no longer presents such risk to protect adequately against such risk using the least burdensome requirements:

#### (b) Risk Evaluations.—

(1) PRIORITIZATION FOR RISK EVALUATIONS.—

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#### (A) IDENTIFICATION OF PRIORITIES FOR RISK EVALUATION.—

- (i) HIGH-PRIORITY SUBSTANCES.—The Administrator shall designate as a high-priority substance a chemical substance that the Administrator concludes, without consideration of costs or other nonrisk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator.
- (ii) LOW-PRIORITY SUBSTANCES.—The Administrator shall designate a chemical substance as a low-priority substance if the Administrator concludes, based on information sufficient to establish, without consideration of costs or other nonrisk factors, that such substance does not meet the standard identified in clause (i) for designating a chemical substance a high-priority substance.

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#### (4) RISK EVALUATION PROCESS AND DEADLINES.—

(A) IN GENERAL.—The Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.

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#### Risk Evaluation Rule §702.47 Unreasonable Risk Determination.

As part of the risk evaluation, EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under each condition of uses within the scope of the risk evaluation, either in a single decision document or in multiple decision documents

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#### SEC. 9. RELATIONSHIP TO OTHER FEDERAL LAWS.

- (a) LAWS NOT ADMINISTERED BY THE ADMINISTRATOR.—(1) If the Administrator determines has reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator, under the conditions of use, and determines, in the Administrator's discretion, that such risk may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by the Administrator, the Administrator shall submit to the agency which administers such law a report which describes such risk and includes in such description a specification of the activity or combination of activities which the Administrator has reason to believe so presents such risk. Such report shall also request such agency—
  - (A)(i) to determine if the risk described in such report may be prevented or reduced to a sufficient extent by action taken under such law, and
    - (ii) if the agency determines that such risk may be so prevented or reduced, to issue an order declaring whether or not the activity or combination of activities specified in the description of such risk presents such risk; and
    - (B) to respond to the Administrator with respect to the matters described in subparagraph (A).

Any report of the Administrator shall include a detailed statement of the information on which it is based and shall be

published in the Federal Register. The agency receiving a request under such a report shall make the requested determination, issue the requested order, and make the requested response within such time as the Administrator specifies in the request, but such time specified may not be less than 90 days from the date the request was made. The response of an agency shall be accompanied by a detailed statement of the findings and conclusions of the agency and shall be published in the Federal Register.

- (2) If the Administrator makes a report under paragraph (1) with respect to a chemical substance or mixture and the agency to which such report was made either—
  - (A) issues an order, within the time period specified by the Administrator in the report, declaring that the activity or combination of activities specified in the description of the risk described in the report does not present the risk described in the report, or
  - (B) responds within the time period specified by the Administrator in the report and initiates, within 90 days of the publication in the Federal Register of the response of the agency under paragraph (1), action under the law (or laws) administered by such agency to protect against such risk associated with such activity or combination of activities, the Administrator may not take any action under section 6(a) or 7 with respect to such risk.
- (3) The Administrator shall take the actions described in paragraph (4) if the Administrator makes a report under paragraph (1) with respect to a chemical substance or mixture and the agency to which the report was made does not—
  - (A) issue the order described in paragraph (2)(A) within the time period specified by the Administrator in the report; or
  - (B)(i) respond under paragraph (1) within the timeframe specified by the Administrator in the report; and
    - (ii) initiate action within 90 days of publication in the Federal Register of the response described in clause (i).
- (4) If an agency to which a report is submitted under paragraph (1) does not take the actions described in subparagraph (A) or (B) of paragraph (3), the Administrator shall—
  - (A) initiate or complete appropriate action under section 6; or
  - (B) take any action authorized or required under section 7, as applicable.
- (5) This subsection shall not relieve the Administrator of any obligation to take any appropriate action under section 6(a) or 7 to address risks from the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or any combination of those activities, that are not identified in a report issued by the Administrator under paragraph (1).
- $(\underline{63})$  If the Administrator has initiated action under section  $\underline{6(a)}$  or 7 with respect to a risk associated with a chemical substance or mixture which was the subject of a report made to an agency under paragraph (1), such agency shall before taking action under the law (or laws) administered by it to protect against such risk consult with the Administrator for the purpose of avoiding duplication of Federal action against such risk.
- (b) LAWS ADMINISTERED BY THE ADMINISTRATOR.—(1) The Administrator shall coordinate actions taken under this Act with actions taken under other Federal laws administered in whole or in part by the Administrator. If the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions taken under this Act. This subsection shall not be construed to relieve the Administrator of any requirement imposed

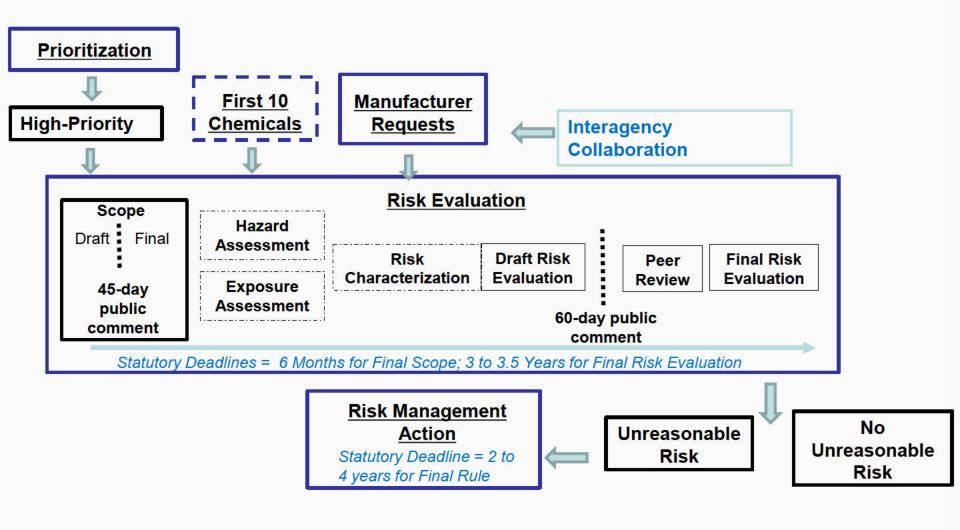
on the Administrator by such other Federal laws.

- (2) If the Administrator determines that a risk of injury to health or the environment could be eliminated or reduced to a sufficient extent by actions taken under another Federal law (or laws) administered in whole or in part by the Administrator, the Administrator may not promulgate a rule under subsection (a) to protect against such risk of injury unless the Administrator finds, in the Administrator's discretion. In making a determination under paragraph (1) that it is in the public interest for the Administrator to take an action under this title with respect to a chemical substance or mixture rather than under another law administered in whole or in part by the Administrator, to protect against such risk under this Act. In making such a finding the Administrator shall consider, based on information reasonably available to the Administrator, (i) all relevant aspects of the risk described in paragraph (1), as determined by the Administrator in the Administrator's discretion, (ii) and a comparison of the estimated costs of complying with actions taken under this Act and under such law (or laws), and (iii) the relative and efficienciesy of the actions to be taken under this title Act and an action to be taken under such other law (or laws) to protect against such risk of injury.
- (c) OCCUPATIONAL SAFETY AND HEALTH.—In exercising any authority under this Act, the Administrator shall not, for purposes of section 4(b)(1) of the Occupational Safety and Health Act of 1970, be deemed to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety and health.
- (d) COORDINATION.—In administering this Act, the Administrator shall consult and coordinate with the Secretary of Health and Human Services, Education, and Welfare and the heads of any other appropriate Federal executive department or agency, any relevant independent regulatory agency, and any other appropriate instrumentality of the Federal Government for the purpose of achieving the maximum enforcement of this Act while imposing the least burdens of duplicative requirements on those subject to the Act and for other purposes. The Administrator shall, in the report required by section 30, report annually to the Congress on actions taken to coordinate with such other Federal departments, agencies, or instrumentalities, and on actions taken to coordinate the authority under this Act with the authority granted under other Acts referred to in subsection(b).
- (e) EXPOSURE INFORMATION.—In addition to the requirements of subsection (a), if the Administrator obtains information related to exposures or releases of a chemical substance or mixture that may be prevented or reduced under another Federal law, including a law not administered by the Administrator, the Administrator shall make such information available to the relevant Federal agency or office of the Environmental Protection Agency.

  [15 U.S.C. 2608]



## Risk Evaluation Process and Timeline





## **Initial 10 Risk Evaluations**

 The list of the initial 10 chemicals was published on Dec. 19, 2016

1, 4 Dioxane
1-Bromopropane
Asbestos
Carbon Tetrachloride
Cyclic Aliphatic Bromide Cluster
(HBCD)

Methylene Chloride
N-Methylpyrolidone
Pigment Violet 29
Trichloroethylene
Tetrachloroethylene

Scope documents published June 22, 2017

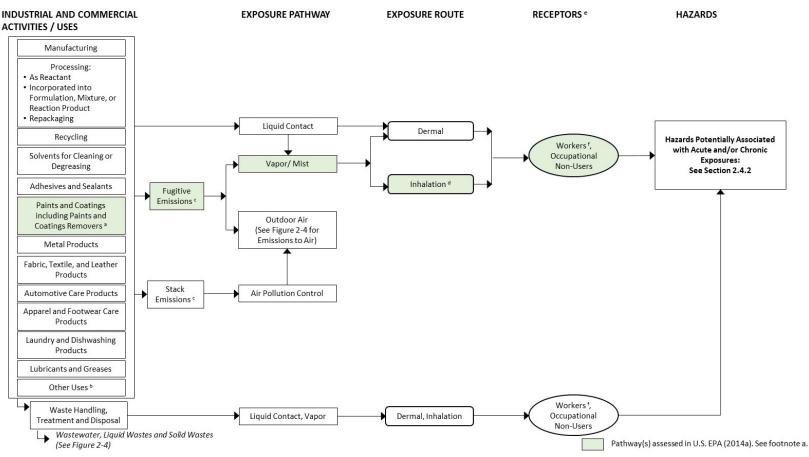


Figure 2-2. Initial Methylene Chloride Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from industrial and commercial activities and uses of methylene chloride.

<sup>&</sup>lt;sup>a</sup> U.S. EPA (2014a) assessed paint removal uses in industrial and commercial settings and therefore those uses are out of scope for the risk evaluation.

<sup>&</sup>lt;sup>b</sup> Some products are used in both commercial and consumer applications such adhesives and sealants. Additional uses of methylene chloride are included in Table 2-3.

<sup>&</sup>lt;sup>c</sup> Stack air emissions are emissions that occur through stacks, confined vents, ducts, pipes or other confined air streams. Fugitive air emissions are those that are not stack emissions and include fugitive equipment leaks from valves, pump seals, flanges, compressors, sampling connections and open-ended lines; evaporative losses from surface impoundment and spills; and releases from building ventilation systems.

<sup>&</sup>lt;sup>d</sup> Exposure may occur through mists that deposit in the upper respiratory tract and are swallowed.

<sup>&</sup>lt;sup>e</sup> Receptors include potentially exposed or susceptible subpopulations.

f When data and information are available to support the analysis, EPA also considers the effect that engineering controls and/or personal protective equipment have on occupational exposure levels.

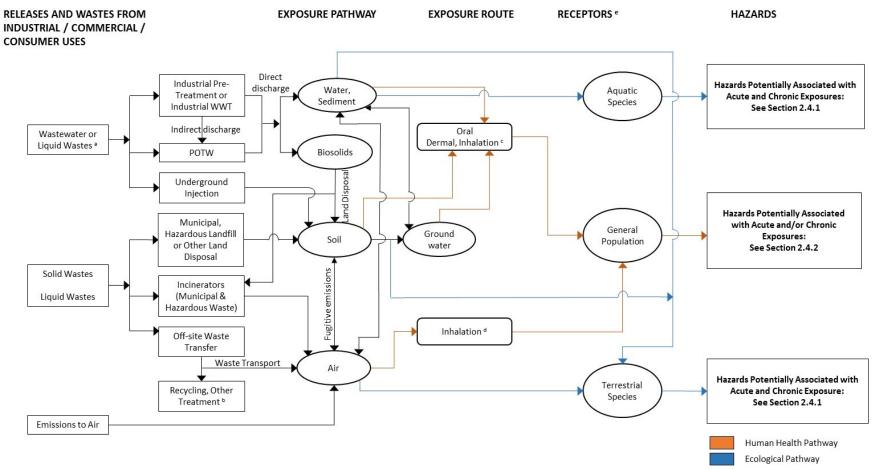


Figure 2-4. Initial Methylene Chloride Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards The conceptual model presents the exposure pathways, exposure routes and hazards to human and environmental receptors from environmental releases and wastes of methylene chloride.

<sup>&</sup>lt;sup>a</sup> Industrial wastewater may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to POTW (indirect discharge). For consumer uses, wastewater may be released directly to POTW (i.e., down the drain). Drinking water will undergo further treatment in drinking water treatment plant. Ground water may also be a source of drinking water.

<sup>&</sup>lt;sup>b</sup> Additional releases may occur from recycling and other waste treatment.

<sup>&</sup>lt;sup>c</sup> Volatilization from or liquid contact with tap water in the home during showering, bathing, washing, etc. represents another potential in-home exposure pathway.

<sup>&</sup>lt;sup>d</sup> Presence of mist is not expected; dermal and oral exposures are negligible.

<sup>&</sup>lt;sup>e</sup> Receptors include potentially exposed or susceptible subpopulations.

### Methylene Chloride Regulatory Landscape

Methylene Chloride is subject to the following EPA-administered statutes/sections

#### Office of Air

Clean Air Act (CAA) – Section 112(b)
 Lists methylene chloride as a HAP (42 U.S. Code section 7412), and is considered an "urban air toxic" (CAA Section 112(k)).

### 2. CAA – Section 112(d)

There are 16<sup>1</sup> source-specific NESHAPs for methylene chloride and 15 Risk and Technology Reviews completed for methylene chloride.

### 3. Clean Air Act – Section 612

Under the SNAP program, EPA listed methylene chloride as an acceptable substitute in multiple industries, including in foam blowing agents for polyurethane, in cleaning solvents, in aerosol solvents and in adhesives and coatings (1994). In 2016, methylene chloride was listed as an unacceptable substitute for use in flexible polyurethane.

#### Office of Water

4. Clean Water Act – Section 304(a)

Under section 304(a), methylene chloride has a national recommended human health ambient water quality criteria.

5. Clean Water Act – Section 307(a)

Methylene chloride is designated as a toxic pollutant under section 307(a)(1) of the CWA and as such is subject to best available technology effluent limitations established on either a national basis through rules (Sections 301(b), 304(b), 307(b), 306) or on a case-by-case best professional judgement basis in NPDES permits (Section 402(a)(1)(B)).

6. Safe Drinking Water Act – Section 1412

Methylene chloride is subject to NPDWR under the SDWA with a MCLG of zero and an enforceable MCL of 0.005 mg/L or 5 ppb (Section 1412).

<sup>&</sup>lt;sup>1</sup> Flexible polyurethane foam production and fabrication process; Aerospace +RTR; Boat manufacturing; Chemical manufacturing industry (agricultural chemicals and pesticides, cyclic crude and intermediate production, industrial inorganic chemicals, industrial and miscellaneous organic chemicals, inorganic pigments, plastic materials and resins, pharmaceutical production, synthetic rubber); Fabric printing, coating and dyeing; Halogenated Solvent Cleaning + RTR; Miscellaneous organic chemical production and processes (MON); Paint and allied products manufacturing (area sources); Paint stripping and miscellaneous surface coating operations (area sources); Paper and other web surface coating; Pesticide active ingredient production +RTR; Pharmaceutical production; Publicly Owned Treatment Works + RTR; Reciprocating Internal Combustion Engines (RICE); Reinforced plastic composites production; Wood preserving (area sources).

### Office of Land and Emergency Response

- 7. Resource Conservation and Recovery Act (RCRA) Section 3001 Methylene chloride is included on the list of hazardous wastes pursuant to RCRA 3001. RCRA Hazardous Waste Code: F001, F002; U080. In 2013, EPA modified its hazardous waste management regulations to conditionally exclude solvent-contaminated wipes that have been cleaned and reused from the definition of solid waste under RCRA (78 FR 46447 July 31, 2013, 40 CFR 261.4(a)(26)).
- 8. Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) Sections 102(a) and 103

  Methylene chloride is a hazardous substance under CERCLA. Releases of methylene chloride in excess of 1,000 pounds must be reported (40 CFR 302.4).

### Office of Pollution Prevention and Toxics

- 9. Emergency Planning and Community Right-to-Know (EPCRA); Section 313 Methylene chloride is a listed substance subject to reporting requirements under 40 CFR 372.65 effective as of January 01, 1987.
- 10. Federal Food, Drug, and Cosmetic Act (FFDCA) Section 408

  Methylene chloride was registered as antimicrobial, conventional chemical in 1974, but this tolerance was revoked in 2002, and there are currently no registrations for use as a pesticide (67 FR 16027, April 4, 2002).
- 11. Toxic Substances Control Act Sections 4 [test rules], 6 [proposed rule on paint strippers]; 8(a)[CDR], 8(b)[TSCA inventory], 8(d)[health& safety studies], 8(e)[information about substantial risk]

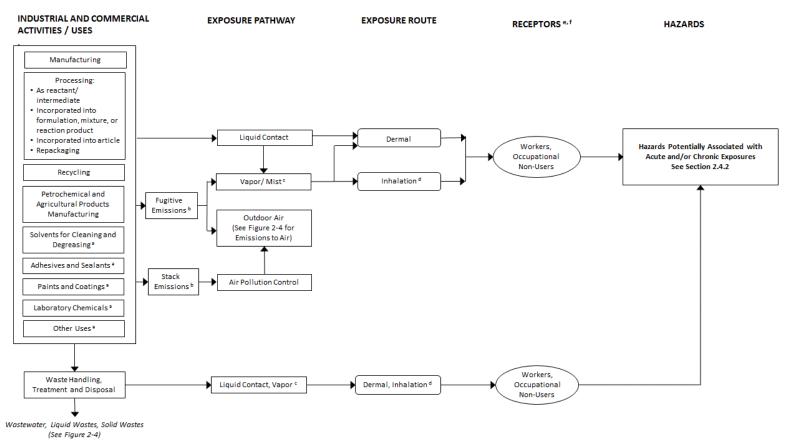


Figure 2-2. Initial Carbon Tetrachloride Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from industrial and commercial activities and uses of carbon tetrachloride.

<sup>&</sup>lt;sup>a</sup> Some products are used in both commercial and consumer applications. Additional uses of carbon tetrachloride are included in Table 2-3.

<sup>&</sup>lt;sup>b</sup> Stack air emissions are emissions that occur through stacks, confined vents, ducts, pipes or other confined air streams. Fugitive air emissions are those that are not stack emissions, and include fugitive equipment leaks from valves, pump seals, flanges, compressors, sampling connections, open-ended lines; evaporative losses from surface impoundment and spills; and releases from building ventilation systems.

<sup>&</sup>lt;sup>c</sup> Includes possible vapor intrusion into industrial or commercial facility from carbon tetrachloride contaminated soil and/or ground water.

<sup>&</sup>lt;sup>d</sup> Exposure through mists that deposit in the upper respiratory tract and are swallowed.

<sup>&</sup>lt;sup>e</sup> Receptors include potentially exposed or susceptible subpopulations.

<sup>&</sup>lt;sup>f</sup>When data and information are available to support the analysis, EPA also considers the effect that engineering controls and/or personal protective equipment have on occupational exposure levels.

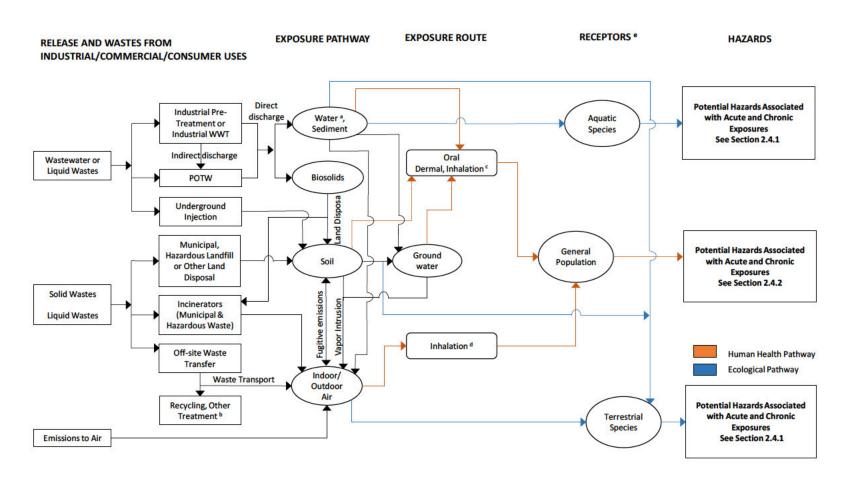


Figure 2-4. Initial Carbon Tetrachloride Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards
The conceptual model presents the exposure pathways, exposure routes and hazards to human and environmental receptors from
environmental releases and wastes of carbon tetrachloride.

<sup>&</sup>lt;sup>a</sup> Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to publicly owned treatment works (POTW) (indirect discharge). For consumer uses, such wastes may be released directly to POTW (i.e., down the drain). Drinking water will undergo further treatment in drinking water treatment plant. Ground water may also be a source of drinking water.

<sup>&</sup>lt;sup>b</sup> Additional releases may occur from recycling and other waste treatment.

<sup>&</sup>lt;sup>c</sup>Volatilization from or liquid contact with tap water in the home during showering, bathing, washing, etc. represents another potential in-home exposure pathway.

<sup>&</sup>lt;sup>d</sup> Presence of mist is not expected; dermal and oral exposure are negligible.

<sup>&</sup>lt;sup>e</sup> Receptors include potentially exposed or susceptible subpopulations.

### Appendix A REGULATORY HISTORY

### A.1 Federal Laws and Regulations

Table\_Apx A-1. Federal Laws and Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
EPA Regulations		
TSCA - Section 6(b)	EPA is directed to identify and begin risk evaluations on 10 chemical substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments.	Carbon tetrachloride is on the initial list of chemicals to be evaluated for unreasonable risk under TSCA (81 FR 91927, December 19, 2016).
TSCA - Section 8(a)	The TSCA section 8(a) CDR Rule requires manufacturers (including importers) to give EPA basic exposure-related information on the types, quantities and uses of chemical substances produced domestically and imported into the United States.	Carbon tetrachloride manufacturing (including importing), processing and use information is reported under the CDR Rule (76 FR 50816, August 16, 2011).
TSCA - Section 8(b)	EPA must compile, keep current and publish a list (the TSCA Inventory) of each chemical substance manufactured, processed, or imported in the United States.	Carbon tetrachloride was on the initial TSCA Inventory and therefore was not subject to EPA's new chemicals review process under TSCA section 5 (60 FR 16309, March 29, 1995).
TSCA - Section 8(d)	Provides EPA with authority to issue rules requiring producers, importers and (if specified) processors of a chemical substance or mixture to submit lists and/or copies of health and safety studies.	Two submissions received (1947-1994) (U.S. EPA, ChemView. Accessed April 13, 2017).
TSCA - Section 8(e)	Manufacturers (including imports), processors and distributors must immediately notify EPA if they obtain information that supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment.	Three submissions received (1992-2010) (U.S. EPA, ChemView. Accessed April 13, 2017).
TSCA - Section 4	Provides EPA with authority to issue rules and orders requiring	Seven section 4 notifications received for carbon tetrachloride:

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	manufacturers (including importers) and processors to test chemical substances and mixtures.	two acute aquatic toxicity studies, one bioaccumulation report and four monitoring reports (1978-1980) (U.S. EPA, ChemView. Accessed April 13, 2017).
EPCRA - Section 313	Requires annual reporting from facilities in specific industry sectors that employ 10 or more full time equivalent employees and that manufacture, process, or otherwise use a TRI-listed chemical in quantities above threshold levels.	Carbon tetrachloride is a listed substance subject to reporting requirements under 40 CFR 372.65 effective as of January 1, 1987.
Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) - Sections 3 and 6	FIFRA governs the sale, distribution and use of pesticides. Section 3 of FIFRA generally requires that pesticide products be registered by EPA prior to distribution or sale. Pesticides may only be registered if, among other things, they do not cause "unreasonable adverse effects on the environment." Section 6 of FIFRA provides EPA with the authority to cancel pesticide registrations if either (1) the pesticide, labeling, or other material does not comply with FIFRA; or (2) when used in accordance with widespread and commonly recognized practice, the pesticide generally causes unreasonable adverse effects on the environment.	Use of carbon tetrachloride as a grain fumigant was banned under FIFRA in 1986 (51 FR 41004, November 12, 1986).
Federal Food, Drug, and Cosmetic Act (FFDCA) - Section 408	FFDCA governs the allowable residues of pesticides in food. Section 408 of the FFDCA provides EPA with the authority to set tolerances (rules that establish maximum allowable residue limits), or exemptions from the requirement of a tolerance, for all residues of a pesticide (including both active and inert ingredients) that are in or on food. Prior to issuing a tolerance or exemption from tolerance, EPA must determine that the tolerance or exemption is "safe."  Sections 408(b) and (c) of the FFDCA define "safe" to mean the Agency has a	EPA removed carbon tetrachloride from its list of pesticide product inert ingredients used in pesticide products in 1998 (63 FR 34384, June 24, 1998).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	reasonable certainty that no harm will result from aggregate exposures to the pesticide residue, including all dietary exposure and all other exposure (e.g., non-occupational exposures) for which there is reliable information. Pesticide tolerances or exemptions from tolerance that do not meet the FFDCA safety standard are subject to revocation. In the absence of a tolerance or an exemption from tolerance, a food containing a pesticide residue is considered adulterated and may not be distributed in interstate commerce.	
CAA - Section 112(b)	This section lists 189 HAPs that must be addressed by EPA and includes authority for EPA to add or delete pollutants. EPA may, by rule, add pollutants that present, or may present, a threat of adverse human health effects or adverse environmental effects.	Lists carbon tetrachloride as a HAP (70 FR 75047, December 19, 2005).
CAA - Section 112(d)	Directs EPA to establish, by rule, NESHAPs for each category or subcategory of major sources and area sources of HAPs. The standards must require the maximum degree of emission reduction that EPA determines is achievable by each particular source category. This is generally referred to as maximum achievable control technology (MACT).	There are a number of source- specific NESHAPs for carbon tetrachloride, including: Rubber tire manufacturing (67 FR 45588, July 9, 2002) Chemical Manufacturing Area Sources (74 FR 56008, October 29, 2009) Use of carbon tetrachloride as a dilutent for NCI3 (59 FR 19402, April 22,1994), Halogenated solvent cleaning operations (59 FR 61801, December 2, 1994) Wood Furniture Manufacturing Operations (60 FR 62930, December 7,1995) Group 1 Polymers and Resins (61 FR 46906, September 5, 1996)

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		Plywood and Composite Wood Products (69 FR 45944, July 30, 2004)
CAA - Section 604	Establishes a mandatory phase-out of ozone depleting substances.	The production and import of most Class I Ozone Depleting Substances (ODS), including carbon tetrachloride, was banned in 1996 (58 FR 65018, December 10, 1993). However, this ban does not apply to production and import of amounts that are transformed. 40 CFR 82.4. "Transform" is defined as "to use and entirely consume (except for trace quantities) a controlled substance in the manufacture of other chemicals for commercial purposes." 40 CFR 82.3.
CWA - Section 304(a)(1)	Requires EPA to develop and publish ambient water quality criteria (AWQC) reflecting the latest scientific knowledge on the effects on human health that may be expected from the presence of pollutants in any body of water.	In 2015, EPA published updated AWQC for carbon tetrachloride, including recommendations for "water + organism" and "organism only" human health criteria for states and authorized tribes to consider when adopting criteria into their water quality standards.
CWA – Sections 301(b), 304(b), 306, and 307(b)	Requires establishment of Effluent Limitations Guidelines and Standards for conventional, toxic, and non-conventional pollutants. For toxic and non-conventional pollutants, EPA identifies the best available technology that is economically achievable for that industry after considering statutorily prescribed factors and sets regulatory requirements based on the performance of that technology.	
CWA - Section 307(a)	Establishes a list of toxic pollutants or combination of pollutants under the CWA. The statute specifies a list of families of toxic pollutants also listed in the Code of Federal Regulations at 40 CFR 401.15. The "priority pollutants" specified by those families are listed in	Carbon tetrachloride is designated as a toxic pollutant under section 307(a)(1) of the CWA and as such is subject to effluent limitations per section 1317 of the Clean Water Act.

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	40 CFR part 423, Appendix A. These are pollutants for which best available technology effluent limitations must be established on either a national basis through rules, see section 301(b), 304(b), 307(b), 306, or on a case-by-case best professional judgment basis in NPDES permits. CWA 402(a)(1)(B).	
SDWA - Section 1412	Requires EPA to publish a non- enforceable maximum contaminant level goals (MCLGs) for contaminants which 1. may have an adverse effect on the health of persons; 2. are known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and 3. in the sole judgment of the Administrator, regulation of the contaminant presents a meaningful opportunity for health risk reductions for persons served by public water systems. When EPA publishes an MCLG, EPA must also promulgate a National Primary Drinking Water Regulation (NPDWR) which includes either an enforceable maximum contaminant level (MCL), or a required treatment technique. Public water systems are required to comply with NPDWRs.	Carbon tetrachloride is subject to National Primary Drinking Water Regulations (NPDWR) under SDWA and EPA has set a MCLG of zero and an enforceable MCL of 0.005 mg/L (56 FR 3526 January 30, 1991).
Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) - Sections 102(a) and 103	Authorizes EPA to promulgate regulations designating as hazardous substances those substances which, when released into the environment, may present substantial danger to the public health or welfare or the environment. EPA must also promulgate regulations establishing the quantity of any hazardous substance the release of which must be reported under Section 103. Section 103 requires persons in charge of vessels or facilities to report to the National Response Center if they	Carbon tetrachloride is a hazardous substance under CERCLA. Releases of carbon tetrachloride in excess of 10 pounds must be reported (40 CFR 302.4).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	have knowledge of a release of a hazardous substance above the reportable quantity threshold.	
RCRA - Section 3001	Directs EPA to develop and promulgate criteria for identifying the characteristics of hazardous waste, and for listing hazardous waste, taking into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue, and other related factors such as flammability, corrosiveness, and other hazardous characteristics.	Carbon tetrachloride is included on the list of hazardous wastes pursuant to RCRA 3001. Two categories of carbon tetrachloride wastes are considered hazardous: discarded commercial chemicals (U211) (40 CFR 261.31(a)), and spent degreasing solvent (F001) (40 CFR 261.33(f)) (45 FR 33084 May 19, 1980).
		RCRA solid waste that leaches 0.5 mg/L or more carbon tetrachloride when tested using the TCLP leach test is RCRA hazardous (D019) under 40 CFR 261.24 (55 FR 11798 March 29, 1990).
		In 2013, EPA modified its hazardous waste management regulations to conditionally exclude solvent-contaminated wipes that have been cleaned and reused from the definition of solid waste under RCRA (40 CFR 261.4(a)(26)) (78 FR 46447, July 31, 2013).
Other Federal Regulati	ions	
Federal Hazardous Substance Act (FHSA)	Requires precautionary labeling on the immediate container of hazardous household products and allows the Consumer Product Safety Commission (CPSC) to ban certain products that are so dangerous or the nature of the hazard is such that required labeling is not adequate to protect consumers.	Use of carbon tetrachloride in consumer products was banned in 1970 by the CPSC (16 CFR 1500.17).
FFDCA	Provides the U.S. Food and Drug Administration (FDA) with authority to	The FDA regulates carbon tetrachloride in bottled water. The maximum permissible level of

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	oversee the safety of food, drugs and cosmetics.	carbon tetrachloride in bottled water is 0.005 mg/L (21 CFR 165.110).  All medical devices containing or manufactured with carbon tetrachloride must contain a warning statement that the compound may destroy ozone in the atmosphere (21 CFR 801.433).  Carbon tetrachloride is also listed as an "Inactive Ingredient for approved Drug Products" by FDA (FDA Inactive Ingredient Database. Accessed April 13, 2017).
OSHA	Requires employers to provide their workers with a place of employment free from recognized hazards to safety and health, such as exposure to toxic chemicals, excessive noise levels, mechanical dangers, heat or cold stress, or unsanitary conditions.	In 1970, OSHA issued occupational safety and health standards for carbon tetrachloride that included a PEL of 10 ppm TWA, exposure monitoring, control measures and respiratory protection (29 CFR 1910.1000).
	Under the Act, OSHA can issue occupational safety and health standards including such provisions as PELs, exposure monitoring, engineering and administrative control measures, and respiratory protection.	OSHA prohibits all workplaces from using portable fire extinguishers containing carbon tetrachloride (29 CFR 1910.157(c)(3)).
Atomic Energy Act	The Atomic Energy Act authorizes the Department of Energy to regulate the health and safety of its contractor employees.	10 CFR 851.23, Worker Safety and Health Program, requires the use of the 2005 ACGIH TLVs if they are more protective than the OSHA PEL. The 2005 TLV for carbon tetrachloride is 5 ppm (8hr Time Weighted Average) and 10 ppm Short Term Exposure Limit (STEL).

### A.2 State Laws and Regulations

Table\_Apx A-2. State Laws and Regulations

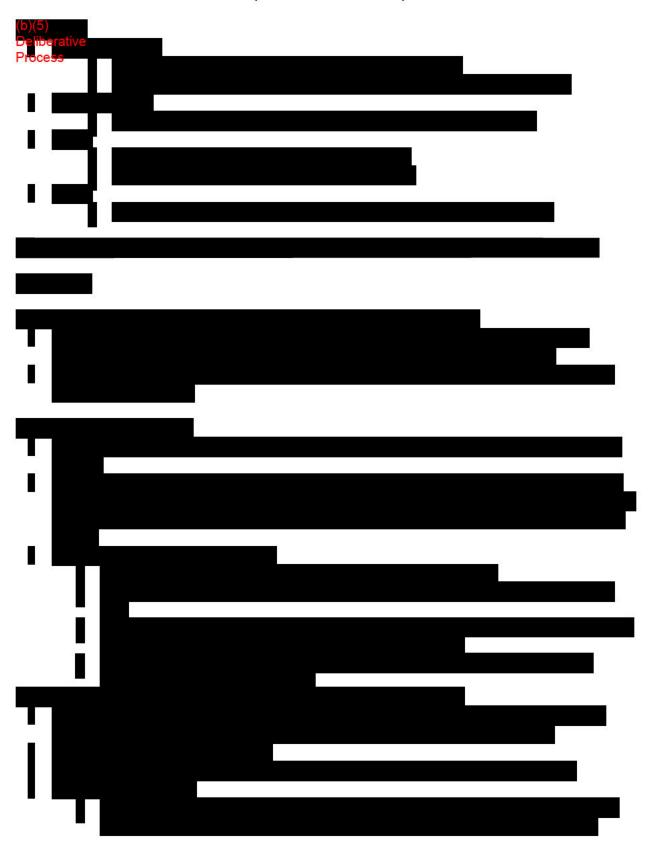
State Actions	Description of Action
State agencies of interest	
State permissible exposure limits	California PEL: 12.6 mg/L (Cal Code Regs. Title 8, section 5155), Hawaii PEL: 2 ppm (Hawaii Administrative Rules section 12-60-50).
State Right-to-Know Acts	Massachusetts (454 Code Mass. Regs. section 21.00), New Jersey (8:59 N.J. Admin. Code section 9.1), Pennsylvania (34 Pa. Code section 323).
State air regulations	Allowable Ambient Levels (AAL): Rhode Island (12 R.I. Code R. 031-022), New Hampshire (RSA 125-I:6, ENV-A Chap. 1400).
State drinking water standards and guidelines	Arizona (14 Ariz. Admin. Register 2978, August 1, 2008), California (Cal Code Regs. Title 26, section 22-64444), Delaware (Del. Admin. Code Title 16, section 4462), Connecticut (Conn. Agencies Regs. section 19-13-B102), Florida (Fla. Admin. Code R. Chap. 62-550), Maine (10 144 Me. Code R. Chap. 231), Massachusetts (310 Code Mass. Regs. section 22.00), Minnesota (Minn R. Chap. 4720), New Jersey (7:10 N.J Admin. Code section 5.2), Pennsylvania (25 Pa. Code section 109.202), Rhode Island (14 R.I. Code R. section 180-003), Texas (30 Tex. Admin. Code section 290.104).
Other	In California, carbon tetrachloride was added to the Proposition 65 list in 1987 (Cal. Code Regs. Title 27, section 27001).  Carbon tetrachloride is on the MA Toxic Use Reduction Act (TURA) list of 1989 (301 Code Mass. Regs. section 41.03).

### A.3 International Laws and Regulations

Table\_Apx A-3. Regulatory Actions by Other Governments and Tribes

Country/Organization	Requirements and Restrictions	
Regulatory Actions by otl	ner Governments and Tribes	
Montreal Protocol	Carbon tetrachloride is considered an ODS and its production and use are controlled under the 1987 Montreal Protocol on Substances That Deplete the Ozone Layer and its amendments (Montreal Protocol Annex B – Group II).	

### Human Health Hazard Assessment: Proposed Milestones and Options





Question: (b)(5) Deliberative Process

Options:



#### **Supplemental Information**

### 1. Brief Study Summary<sup>1</sup>

In a combined chronic toxicity/carcinogenicity study in rats (OPPTS 870.4300; OECD 453), the test compound was administered to rats (80/sex/group) by oral gavage for up to 104 weeks. A cohort of 10/sex/group were terminated at 12 months (interim sacrifice). Dose levels were 0, 0.1, 1 or 50 mg/kg-bw/day for males and 0, 1, 50 or 500 mg/kg-bw/day for females. With respect to non-cancer findings in males at 50 mg/kg-bw/day, increased incidences of focal cystic degeneration and centrilobular hepatocellular necrosis of the liver were observed microscopically, with associated increases in enzymes indicative of liver injury as well as centrilobular hepatocellular hypertrophy. At 500 mg/kg-bw/day, findings in females included reductions in body weight, body weight gain, and food efficiency; decreases in red cell mass with corresponding increases in reticulocytes; and microscopic findings in the liver, kidney, nonglandular stomach, and tongue. In the liver, there were increased incidences of focal cystic degeneration, individual hepatocyte necrosis, and centrilobular hepatocyte necrosis, as well as panlobular and centrilobular hypertrophy. For males, a NOAEL for systemic toxicity was 1 mg/kg-bw/day based on liver effects at 50 mg/kg-bw/day. For females, the NOAEL for systemic toxicity was 50 mg/kg-bw/day based on numerous effects at 500 mg/kg-bw/day.

#### **Neoplastic Findings:**

<u>Females.</u> An induction of liver cancer was observed but only at the highest dose, where degenerative and necrotic changes also occurred in the liver. The tumor incidences were 0/70 (0%), 0/70 (0%), 0/70 (0%), and 11/70 (15.7%) for hepatocellular adenomas and 0/70 (0%), 0/70 (0%), 0/70 (0%), and 4/70 (5.7%) for hepatocellular carcinomas at the doses of 0, 1, 50, and 500 mg/kg-bw/day, respectively. The increased incidences of hepatocellular adenomas and carcinomas at the high dose were statistically significant and also exceeded the test laboratory historical control ranges 0-5% and 0-1.7% for adenomas and carcinomas, respectively.

Males: There was a statistically significant increase in the incidence of pancreatic acinar cell adenomas/carcinomas combined (but not adenomas or carcinomas alone) at 50 mg/kg-bw-day. Incidences of adenomas were 0/70, 1/70 (1.4%), 0/70 (0%), 3/70 (4.3%) at 0, 0.1, 1, and 50 mg/kg-bw/day, respectively (not statistically significant; within the test laboratory historical control range of 0-5%). The incidence of pancreatic acinar cell carcinomas was 0/70 (0%) in all groups other than the high dose group where 2/70 (2.9%) were observed (not statistically significant; slightly higher than upper end of historical control range of 0-1.7%). When combined, the incidences of adenoma/carcinoma were 0/70 (0%), 1/70 (1.4%), 0/70 (0%), 5/70 (7.1%) at 0, 0.1, 1, and 50 mg/kg-bw/day, respectively, with the increased incidence at the high dose statistically significant (trend test and Peto test). For reference, the incidences of pancreatic acinar cell hyperplasia were 16/70 (22.9%), 18/70 (25.7%), 7/70 (10%), and 21/70 (30%) at 0, 0.1, 1, and 50 mg/kg-bw/day, respectively. The increased incidence of hyperplasia at the high dose was not statistically significant, and a dose-related increase in the incidence across the range of doses tested was not apparent.

In the testes, the incidences of interstitial cell adenomas were 4/70 (5.7%), 4/70 (5.7%), 1/70 (1.4%), and 8/70 (11.4%) at 0, 0.1, 1, and 50 mg/kg-bw/day, respectively. In addition, an interstitial cell adenoma was present in 1/10 high dose males at the interim sacrifice. The increased incidence at 50 mg/kg-

<sup>&</sup>lt;sup>1</sup> In addition to submission of the full study report to EPA, this study was published in the scientific literature; Citation: JM Rae et al. Evaluation of chronic toxicity and carcinogenicity of ammonium 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)-propanoate in Sprague-Dawley rats. Toxicology Reports 2 (2015) 939-949.

bw/day (11.4%) was not statistically significant, but was slightly greater than the upper end of the testing laboratory's historical control range (0-8.3%). For reference, the incidences of interstitial cell hyperplasia were 7/70 (10%), 7/70 (10%), 3/70 (4.3%), and 15/70 (21.4%) at 0, 0.1, 1, and 50 mg/kg-bw/day, respectively. The increased incidence of hyperplasia at the high dose was not statistically significant and while the incidence of hyperplasia at 50 mg/kg-bw/day exceeded the historical control range (0-8.3%), incidences in the control and low dose groups (both 10%) did also.

### Study Author Conclusions Regarding Liver, Pancreatic, and Testicular Tumor Findings.

The study authors noted that the test article belongs to a class compounds knowns as peroxisome proliferators (PPARα agonists), which produce liver, pancreatic, and testicular tumors in rodents. The study authors concluded that neoplastic findings in the liver, pancreas, and testes were not likely relevant to humans based on the following: "most research indicates that induction of these specific tumors in rats by non-genotoxic peroxisome proliferators likely has little or no relevance to humans, especially in plausible human exposure scenarios; the test material was determined to be non-genotoxic based on a battery of in vivo and in vitro genotoxicity studies; liver tumors were produced only in females and only at doses associated with marked hepatic and systemic toxicity (including lethality); and thresholds were established for all tumor types." For the liver, the study authors noted that the increased incidences of tumors in high dose females occurred in association with degenerative/necrotic changes in the liver at this dose level. For the pancreatic findings, the study authors indicate that while there were statistically significant increases in the incidence of acinar cell adenoma/carcinoma combined in high dose males which were slightly outside the historical control range, the increases in adenoma or carcinoma alone and hyperplasia were not statistically significant. Given this along with PPARα agonist activity of the test compound, the study authors considered the marginal increase in pancreatic acinar cell tumors in the 50 mg/kg-bw/day male group as equivocal evidence of a test articlerelated effect. For the testes, the study authors concluded that the potential relationship of interstitial cell adenomas and hyperplasia observed at the high dose relative to treatment with test compound cannot be ruled out given that PPARa agonists are known to produce proliferative interstitial cell lesions in the testes of rats. The testicular findings were concluded by the study authors to be equivocal however, given the marginal increase in the incidences of adenomas and hyperplasia, the lack of statistical significance, and the incidences of these findings in concurrent controls.

2. "Questions and Answers Regarding North Carolina Department of Health and Human Services Updated Risk Assessment for GenX (Perfluoro-2-propoxypropanoic acid)" available at <a href="https://files.nc.gov/ncdeq/GenX/NC%20DHHS%20Risk%20Assessment%20FAQ%20Final%20Clean%20071417%20PM.pdf">https://files.nc.gov/ncdeq/GenX/NC%20DHHS%20Risk%20Assessment%20FAQ%20Final%20Clean%20071417%20PM.pdf</a>

This document states "Although the preliminary assessment was based upon a study with combined cancer and non-cancer endpoints, the updated health goal considers non-cancer endpoints only. There are no studies in humans on cancer related to GenX. Only one animal study is available for cancer analysis, and it has shown increases in certain cancers. Based on conversations with EPA, there is not enough information at this time to identify a specific level of GenX that might be associated with an increased risk for cancer."

### DRAFT: Federal Information Exchange on PFAS

February 5–6, 2018 Natcher Conference Center E1/E2, A, and G1/G2 Bethesda, MD 20892-2152

<u>Description:</u> The Federal Information Exchange on PFAS is sponsored by the Toxics & Risks Subcommittee of the NSTC Committee on Environment, Natural Resources, and Sustainability, co-chaired by the DoD, EPA, and NIH. Participants will share emerging impactful data and improve understanding of the science behind decision-making regarding PFAS. This workshop aims to establish a foundation of common knowledge across federal agencies, and to facilitate future information-sharing across federal agencies, from high-level officials to laboratory researchers.

Workshop Format: This one and a half day workshop will begin the afternoon of February 5<sup>th</sup> with opening remarks from senior government leaders such as Dr. Linda Birnbaum, Director of the National Institute of Environmental Health Sciences; Dr. Patrick Breysse, Director of the National Center for Environmental Health; Ms. Maureen Sullivan, Deputy Assistant Secretary of Defense, Environment, Safety & Occupational Health; and Dr. Jennifer Orme-Zavaleta, Principal Deputy Assistant Administrator for Science, USEPA Office of Research and Development. A panel discussion will feature issues confronting state health officials. Leading federally-funded researchers will give plenary lectures about new findings in their respective areas of expertise. On February 6<sup>th</sup>, federal employees and federally-funded researchers will participate in breakout sessions to establish current scientific knowledge and future directions within key topic areas, to be reported in a panel discussion. Specific topics are to-be-determined but may include:



A final session will discuss risk assessment, consideration of data needs for health-based values, and ongoing coordination and communication across federal agencies. The workshop will be immediately followed by a closed Toxics & Risks Subcommittee meeting to discuss how these findings will inform agencies moving forward.

### **Objectives:**

Workshop participants will emerge with:

- Informed current understanding of PFAS knowledge and knowledge gaps, across participating federal agencies; and
- Operational-level cooperation and collaboration among decision-makers and those who
  are effecting the science at the lab bench and in the field.

Toxics and Risks Subcommittee will make progress toward:

- Common knowledge basis to inform policy-makers within various federal agencies;
- Report-out list of needs to inform future federal PFAS strategy; and
- Continued open communication among agencies.

## Overview of Reg Neg Mandate; FACA Rules and Reg Neg Process

For OPPT IO 5/15/17

## Overview of the Reg Neg Mandate

- On June 22, 2016, TSCA was amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act to include the requirement that EPA convene a negotiated rulemaking to develop and publish a proposed rule providing for limiting the reporting requirements under TSCA section 8(a) for manufacturers of any inorganic byproducts, when such byproducts, whether by the byproduct manufacturer or by any other person, are subsequently recycled, reused, or reprocessed.
- ► The Act also required the EPA to publish a final rule resulting from the negotiated rulemaking not later than three and one-half years after June 22, 2016. (See TSCA section 8(a)(6))

## Overview of the Reg Neg Mandate (continued)

- If there is a consensus within the Negotiated Rulemaking Committee, EPA will use the consensus to the maximum extent possible, consistent with the legal obligations of the Agency, as the basis for a rule proposed by the Agency for public notice and comment.
- The Agency is committed to working in good faith to seek consensus on a proposal that is consistent with the legal mandate of TSCA.
- ► The objective of the negotiated rulemaking process is to develop and publish a proposed rule by June 22, 2019.
  - In the event a proposed ruled is developed, a final rule "resulting from such negotiated rulemaking" must be issued by December 22, 2019.

### **FACA Function**

- The sole function of an EPA advisory committee is to provide advice and recommendations to EPA.
- The sole function of a subcommittee or workgroup is to provide advice and recommendations to the parent committee; a subcommittee or workgroup may not provide advice directly to EPA.

## FACA § 5(b) - Balance

FACA requires the membership of each advisory committee "to be fairly balanced in terms of the points of view represented and the functions to be performed."

## Negotiated Rulemaking: Description

- A balanced group of stakeholder representatives that
- Is chartered as a Federal Advisory (FACA) committee
- Joins with Federal representative
- Prior to the publication of an Notice of Proposed Rulemaking (NPRM)
- To negotiate the text or outline of a proposed rule
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## Why then a Reg Neg?

- Statutory requirement
- Parties contribute their knowledge & constraints to seek mutually acceptable requirements
- Joint decision making = greater commitment
- ▶ If agreement reached, quicker implementation
- Can be less costly than litigation & delays due to dissatisfied stakeholders

## Negotiated Rulemaking Process

Before - Convening

- Agency interest in Reg Neg
- Select facilitator
- Conduct convening assessment
- Plan & organize the process
- Obtain FACA charter
- Identify & invite participants

During - Negotiations

- Assemble, analyze, agree on data
- Consult constituents
- Construct and analyze options
- Constituent ratification
- Finalize agreement

After – NPRM

- Final Agency
  Review
- OMB Review
- Administrator signs
- NPRM Published
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## AGENCY RESPONSIBILITES

- Provide leadership (ideas, schedule, options)
- Articulate Agency's needs and constraints
- Provide definition, direction, & decisions in a timely manner
- Provide resources
- Provide data and information
- Keep promises
- Comply with FACA and other requirements



## **CONSENSUS** on the Agreement

- ▶ The final agreement is a <u>package</u> of items on which all members of a group can agree
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### 1st Public Meeting

- FRN published 5/5/17
- Reviews: wkgrp, OPPT IO, AA sig.
- Meeting held 5/9-10/17

### **FACA Charter**

- Establishes Committee, identifies scope and time period
- Reviews: wkgrp, OPPT IO, OCSPP IO
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- Meeting planned for 6/8-9/17
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### Subsequent FACA meetings

 Meetings and negotiations planned to continue, under conditions of the Operating Protocol

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- Describes structure, roles, and rules of Committee.
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### TSCA Lead Hazard Reduction Program Overview

August 2017

### The Lead Paint Problem in the U.S.

- Lead is a potent neurotoxin that causes irreversible damage. CDC states that no level of lead in a child's blood can be specified as safe.
- The most common source of lead exposure for children today is lead paint in older housing and the contaminated dust and soil it generates. Housing units constructed before 1950 are most likely to contain lead-based paint (LBP). The most recent national survey estimated that 37.1 million homes in the United States have some LBP.
- Childhood blood lead levels have declined substantially since the 1970s, due largely to the phasing out of lead in gasoline and to the reduction in the number of homes with lead-based paint hazards.
  - $\circ~1.2\%$  of children had BLL  $\geq 5~\mu g/dL$  in 2011–2014, compared with 26% in 1988–1994 and 8.7% in 1999-2002

### EPA's Statutory Responsibilities under the Residential LBP Hazard Reduction Act of 1992 (Title X)

Title X assigns responsibilities to Federal Agencies with the overall goal of developing a "...national strategy to build the infrastructure necessary to eliminate LBP hazards in all housing as expeditiously as possible." Under Title X, EPA must:

- Establish hazard standards pursuant to TSCA § 403 completed in 2001 (current subject of litigation)
- Regulate LBP activities (abatement, inspection and risk assessment) in target housing and child-occupied facilities pursuant to TSCA § 402 (completed in 1996)
- Regulate renovation, repair and painting (RRP) in homes with LBP pursuant to TSCA § 402 (completed in 2008); Evaluate if hazards are created by RRP activities in public and commercial buildings with LBP; if so, promulgate regulations pursuant to TSCA § 402 (limited work ongoing; current subject of litigation)
- Regulate the identification and/or removal of lead-based paint from bridges, or other structure or super-structures pursuant to TSCA § 402 (no work underway)
- Authorize State and Tribal programs interested in administering the LBP program, pursuant to TSCA § 404 (ongoing)
  - o EPA provides grants to authorized programs to implement LBP regulations
  - \$13.8m in STAG funds in FY17; Approximately \$10.9m is provided to authorized programs, while the remainder is used to support direct implementation by EPA, including development, operations and maintenance of the Federal Lead-based Paint Program database (FLPP)
  - o EPA is required by statute to implement these programs in non-authorized areas
  - o 39 States, DC, Puerto Rico, and 4 tribes are authorized to administer an abatement program
  - o 14 States and the Bois Forte Tribe are currently authorized to administer an RRP program
- Regulate information disclosure standards (with HUD) pursuant to § 1018 of Title X (completed in 1996)
- Establish laboratory standards pursuant to TSCA § 405 -- National Lead Laboratory Accreditation Program (ongoing)
- Work with HUD and CDC to educate the public about lead poisoning pursuant to TSCA § 405 (ongoing)
  - o National Lead Information Center (co-funded with HUD through IAG) supports bilingual toll-free hotline handles ~21,000 contacts per year and distributes ~125,000 documents per year
  - OPPT also conducts general outreach and RRP outreach as funding allows to increase compliance with RRP and to increase public awareness of lead exposure hazards and lead poisoning prevention. Activities have included:
    - o Development and dissemination of brochures and materials
    - Coordinating ad campaigns

- National Lead Poisoning Prevention Week in October
- o EPA's Lead Website
- Partnerships with national contractor locator organizations, including Angie's List, Consumers' CHECKLIST, and Best Picks
- Regional RRP Lead-Safe Certification training and outreach events in 6 Cities in 2016/2017. Follow-up enforcement activities planned for Spring/Summer of 2017:
  - Oakland, Memphis, El Paso, Denver, Kansas City, Baltimore

### **Current Issues**

- Lead Hazard Standards On August 10, 2009, EPA received a petition requesting that EPA take action to lower EPA's regulatory dust lead hazard standards. On October 22, 2009, EPA agreed to initiate a proceeding to determine whether the dust lead hazard standards should be revised. On August 24, 2016, advocates filed a petition in the U.S. Court of Appeals for the Ninth Circuit, asking the court to compel EPA to make such a revision. On January 17, 2017, EPA filed its response brief and declaration, and petitioner's reply brief was filed on January 27, 2017. In the signed declaration, EPA explained that it intends to issue a proposed rule revising the dust lead hazard standards and clearance levels or conclude that no such revision is necessary in an estimated four years. Oral argument before the 9th Circuit was held on June 12, 2017. It is not known when the court will rule in this matter.
- <u>Test Kits</u> No test kit that meets the positive response criterion (i.e. detects lead-based paint at the regulatory lead concentration) specified in the RRP Rule has been approved for use. Note that three kits are approved that meet the negative response criterion (no lead present). The lack of lead test kits meeting the positive response criterion has been controversial, resulting in several congressional letters, two petitions, and failed bills seeking to prohibit the use of EPA resources to implement RRP. Test kits were also mentioned in recent appropriations language.
- <u>Statutory Definition Changes</u> The statutory definition of target housing was recently changed. HUD will update their regulations (b)(5) <u>Deliberative Process</u>
- 610 Review Section 610 of the Regulatory Flexibility Act requires that federal agencies review
  each rule that has or will have a significant economic impact on a substantial number of small
  entities (SISNOSE) within ten years of publication of the final rule. The 610 Review for the RRP
  rule is due in April, 2018.
- Public and Commercial Buildings (P&CBs) EPA was sued on the 2008 RRP rule for failing to
  meet its statutory obligation to address renovations in P&CBs. The resultant settlement agreement
  included establishment of a timeline for action on renovations in P&CBs. Following several
  amendments of the agreement, the most recent deadline for issuing a proposed rule was March 31,
  2017, which EPA did not meet. A new schedule has not been established.
- <u>FY 18 President's Budget</u> The FY 18 President's Budget virtually eliminates the Lead Hazard Reduction Program except for application processing and database management. Under the proposed budget, only the following activities would continue, but at a significantly reduced level:
  - Management of the FLPP database
  - Certification of firms and individuals for the abatement and RRP programs in all nonauthorized states and tribes
  - Accreditation of training providers

### **Byproducts Working Group (As of 8/25/17)**

Designates lead for convening and keeping the Working Group on track. The goal is to send all updates to the full Committee on Sept 6, 2017.

### **Primary Working Groups:**

### **Approach A Exemptions**

- American Fuel and Petrochemical Manufacturers (AFPM): David Dunlap
- Earthworks: Aaron Mintzes
- EPA: Lynn Vendinello
- National Tribal Toxics Council (NTTC): Kristin K'eit or Fred Corey
- Natural Resources Defense Council (NRDC): David Lennett
- North American Metals Council (NAMC): Kathleen Roberts
- State Rep: John Gilkeson or Mark Smith

### Approach A – Option of Reporting via Categories

- American Petroleum Institute (API): Uni Blake
- Association Connecting Electronics Industries (IPC): Bret Bruhn
- EPA: Susan Sharkey
- Guardian Industries Corp.: James Riley
- International Precious Metals Institute (IPMI): Gus Ruggiero
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### Approach A - Part 3 Data

- EPA: Susan Sharkey
- National Tribal Toxics Council (NTTC): Kristin K'eit or Fred Corey
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### Additional Working Groups:

**Approach E - Limit Reporting for Site-Specific Catalyst Recycling:** As of 9/6, the current draft proposal provided by Industry doesn't make sense, and clarifying questions have not been addressed. Information provided seems to indicate that guidance is likely to be sufficient to clarify catalyst recycling issues. **Approach F - Limit Reporting for Reuse of Inorganic Byproducts:** As of 9/6, there is no proposal

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